DOCKET

SUPREME COURT
OF THE UNITED STATES

No. 12-761
Title: POM Wonderful LLC, Petitioner
v.
The Coca-Cola Company
Docketed: December 26, 2012
Linked with 12A420
Lower Ct: United States Court of Appeals for the Ninth Circuit
Case Nos.: (10-55861)
Decision Date: May 17, 2012
Rehearing Denied: August 8, 2012
Questions Presented

~~Date~~~	~~~~~~~Proceedings and Orders~~~~~~~~~~~~~~~~~~~~
Oct 25 2012	Application (12A420) to extend the time to file a petition for a writ of certiorari from November 6, 2012 to December 21, 2012, submitted to Justice Kennedy.
Oct 31 2012	Application (12A420) granted by Justice Kennedy extending the time to file until December 21, 2012.
Dec 21 2012	Petition for a writ of certiorari filed. (Response due January 25, 2013)
Jan 10 2013	Order extending time to file response to petition to and including February 25, 2013.
Feb 22 2013	Brief of respondent The Coca-Cola Company in opposition filed.
Mar 6 2013	DISTRIBUTED for Conference of March 22, 2013.
Mar 7 2013	Reply of petitioner POM Wonderful LLC filed. (Distributed)
Mar 25 2013	The Solicitor General is invited to file a brief in this case expressing the views of the United States. Justice Breyer took no part in the consideration or decision of this petition.
Nov 27 2013	Brief amicus curiae of United States filed.
Dec 10 2013	Supplemental brief of petitioner POM Wonderful LLC filed.
Dec 11 2013	DISTRIBUTED for Conference of January 10, 2014.
Dec 17 2013	Supplemental brief of respondent The Coca-Cola Company filed. (Distributed)
Jan 10 2014	Petition GRANTED. Justice Breyer and Justice Alito took no part in the consideration or decision of this petition.
Feb 11 2014	SET FOR ARGUMENT ON Monday, April 21, 2014
Feb 14 2014	Record received from U.S.C.A. 9th Circuit is electronic and located on PACER.
Feb 14 2014	Record received from U.S.D.C. Central District of California is located on PACER. A portion of this record is SEALED.

Feb 24 2014	Joint appendix filed. (Statement of costs filed.)
Feb 24 2014	Brief of petitioner POM Wonderful LLC filed.
Mar 3 2014	Brief amicus curiae of the United States in support of neither party filed.
Mar 3 2014	Brief amicus curiae of International Trademark Association filed.
Mar 3 2014	Brief amicus curiae of Generic Pharmaceutical Association in support of neither party filed.
Mar 3 2014	Brief amicus curiae of Alaska, et al. filed.
Mar 3 2014	Brief amicus curiae of FDA Commissioner Dr. Donald Kennedy filed.
Mar 3 2014	Brief amicus curiae of The American Intellectual Property Law Association in support of neither party filed.
Mar 3 2014	Brief amici curiae of Public Citizen, Inc., et al. filed.
Mar 10 2014	CIRCULATED.
Mar 26 2014	Brief of respondent The Coca-Cola Company filed. (Distributed)
Apr 2 2014	Motion of the Solicitor General for leave to participate in oral argument as amicus curiae and for divided argument filed.
Apr 2 2014	Brief amicus curiae of Dr. Michael Friedman, Former Acting Commissioner and Lead Deputy Commissioner for the United States FDA filed. (Distributed)
Apr 2 2014	Brief amicus curiae of American Beverage Association filed. (Distributed)
Apr 2 2014	Brief amici curiae of The Chamber of Commerce of the United States of America, et al. filed. (Distributed)
Apr 2 2014	Brief amicus curiae of DRI - The Voice of the Defense Bar filed.
Apr 11 2014	Reply of petitioner POM Wonderful LLC filed. (Distributed)
Apr 16 2014	Justice Alito is no longer recused in this case.
Apr 18 2014	Motion of the Solicitor General for leave to participate in oral argument as amicus curiae and for divided argument GRANTED. Justice Breyer took no part in the consideration or decision of this motion.
Apr 21 2014	Argued. For petitioner: Seth P. Waxman, Washington, D. C. For the United States, as amicus curiae: Melissa Arbus Sherry, Assistant to the Solicitor General, Department of Justice, Washington, D. C. For respondent: Kathleen M. Sullivan, New York, N. Y.
Jun 12 2014	Judgment REVERSED and case REMANDED. Kennedy, J., delivered the opinion of the Court, in which all other Members joined, except Breyer, J., who took no part in the consideration or decision of the case.
Jul 14 2014	JUDGMENT ISSUED.

PETITION FOR WRIT OF CERTIORARI

No. 12-

IN THE

Supreme Court of the United States

POM WONDERFUL LLC,

Petitioner,

v.

THE COCA-COLA COMPANY,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether the court of appeals erred in holding that a private party cannot bring a Lanham Act claim challenging a product label regulated under the Food, Drug, and Cosmetic Act.

PARTIES TO THE PROCEEDING

Petitioner Pom Wonderful LLC was the plaintiff in the district court and the appellant in the court of appeals.

Respondent The Coca-Cola Company was the defendant in the district court and the appellee in the court of appeals.

RULE 29.6 DISCLOSURE

Pom Wonderful LLC is directly owned by Roll Global LLC and ultimately owned by Stewart and Lynda Resnick as trustees of the Stewart & Lynda Resnick Revocable Trust. No publicly held company holds any interest in the Stewart & Lynda Resnick Revocable Trust.

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ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

Pom Wonderful LLC ("Pom") respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Ninth Circuit in this case.

OPINIONS BELOW

The opinion of the court of appeals (App. 1a-14a) is reported at 679 F.3d 1170. The opinion of the district court granting in part and denying in part the parties' motions for summary judgment (App. 21a-73a) is reported at 727 F. Supp. 2d 849. The district court's relevant prior orders in the case (App. 75a-101a) are unreported.

JURISDICTION

The court of appeals entered judgment on May 17, 2012. The court denied Pom's petition for rehearing and rehearing en banc on August 8, 2012. *See* App. 15a-16a. On October 31, 2012, Justice Kennedy extended the time within which to file a petition for a writ of certiorari to and including December 21, 2012. This Court has jurisdiction under 28 U.S.C. § 1254(1).

RELEVANT STATUTORY PROVISIONS

The relevant provisions of the Lanham Act, 15 U.S.C. §§ 1051 *et seq.*, and the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, are reproduced at App. 103a-111a.

INTRODUCTION

The Coca-Cola Company ("Coca-Cola") sells a "Pomegranate Blueberry" juice product that consists of only 0.3% pomegranate juice and 0.2% blueberry juice. Pom brought suit under the Lanham Act to challenge Coca-Cola's deceptive labeling and advertising of this product. In support of its claim, Pom presented evidence that Coca-Cola's label actually misleads consumers regarding the amount of pomegranate and blueberry juice the product contains and that Coca-Cola knew the label would have this misleading effect. Without considering this evidence, the district court rejected Pom's Lanham Act claim on the ground that it was implicitly barred by the FDCA. The court of appeals affirmed, also concluding that the Lanham Act had been silently displaced by the FDCA.

The court of appeals did not rely on any actual provision of statutory text—either in the Lanham Act or the FDCA—to support its conclusion that Pom's Lan-

ham Act claim could not proceed. Rather, it held that Pom's Lanham Act claim was foreclosed merely because Coca-Cola's misleading label is subject to assertedly "comprehensive" regulation by the Food and Drug Administration ("FDA") under the FDCA and, "as best [the court] c[ould] tell," the FDA had not prohibited Coca-Cola's labeling. The court of appeals' ruling conflicts with this Court's precedents governing how courts should reconcile potentially overlapping federal statutes and creates a conflict among the courts of appeals on the important question of whether false labeling claims are actionable under the Lanham Act notwithstanding regulation by the FDA under the FDCA.

As an initial matter, the decision below disregards this Court's repeated instruction that courts must give full effect to allegedly competing federal statutes unless they are in "irreconcilable conflict." That standard is dictated by principles of separation of powers and requires that a court adhere to the statutes Congress enacts—even where the court believes that it would be sensible to give one statute priority over another—unless a direct conflict prevents it from doing so. Here, the Lanham Act and the FDCA are not in irreconcilable conflict and, as a result, can both be given full effect.

As this Court made clear in *Wyeth* v. *Levine*, 555 U.S. 555 (2009), the FDCA sets a floor for regulation upon which other laws can build, not a ceiling. The FDA's authority to make decisions under the FDCA does not reach so far as to preempt all parallel regimes. The Lanham Act, like the state tort regime at issue in *Wyeth*, simply provides an additional layer of protection that the FDCA does not address. Yet, rather than ask whether the Lanham Act and the FDCA are in "irreconcilable conflict," the court of appeals displaced the Lanham Act based on the FDA's supposed "compre-

hensive" regulation of juice labeling and the court's apparent conclusion that Coca-Cola's product complied with that regulation. That holding cannot be squared with the plain terms of the FDCA and the Lanham Act or with this Court's precedents, including *Wyeth*.

The decision below also conflicts with decisions of the Third, Eighth, and Tenth Circuits. Those courts have all held that false labeling or advertising claims are actionable under the Lanham Act notwithstanding federal regulation of the labeling or advertising. Under those circuits' precedents, Pom's claim that Coca-Cola's label misleads consumers would not be barred because it is not an attempt by a private party to *enforce* the FDCA, which is prohibited by the plain text of the statute. The Ninth Circuit had previously applied the same rule, but it abandoned that test in this case in favor of its "comprehensive regulation" inquiry. The resulting circuit split means that Lanham Act suits like Pom's may proceed in the Third, Eighth, and Tenth Circuits, but will be barred in the Ninth Circuit.

If allowed to stand, the Ninth Circuit's opinion would have far-reaching consequences. The decision forecloses challenges to misleading labels by private parties under the Lanham Act, leaving regulation of food and beverage labels almost entirely to the FDA. Yet, as the Government Accountability Office ("GAO") explained in a 2008 report, the FDA's efforts to regulate food labeling leave significant gaps. The GAO concluded that the FDA was understaffed and underfunded and that it was not aggressively policing food labeling. Most critically, the GAO noted that the FDA itself had conceded that the "agency generally does not address misleading food labeling because it lacks the resources to conduct the substantive, empirical research on consumer perceptions that it believes it would need

to legally demonstrate that a label is misleading." The court of appeals' decision is thus not merely wrong but also highly detrimental; it leaves no effective means of preventing all but a small portion of the misleading labeling of food and beverages.

The court of appeals' expansive reasoning would also extend beyond juice labeling to food and other products whose labels are subject to regulation by the FDA or even other agencies. In fact, the decision has already been applied to bar a Lanham Act challenge to a product label regulated by the U.S. Department of Agriculture. The Ninth Circuit's decision also calls into question other statutory regimes in which Congress has authorized private parties to enforce a statute alongside federal regulators. Under the Ninth Circuit's reasoning, any time an agency has broad authority to regulate in a given sphere, that regulation could preclude private actions under entirely different statutes.

The Ninth Circuit's decision thus not only conflicts with decisions of this Court and other courts of appeals, but also raises a question of exceptional importance. This Court should grant the petition for a writ of certiorari.

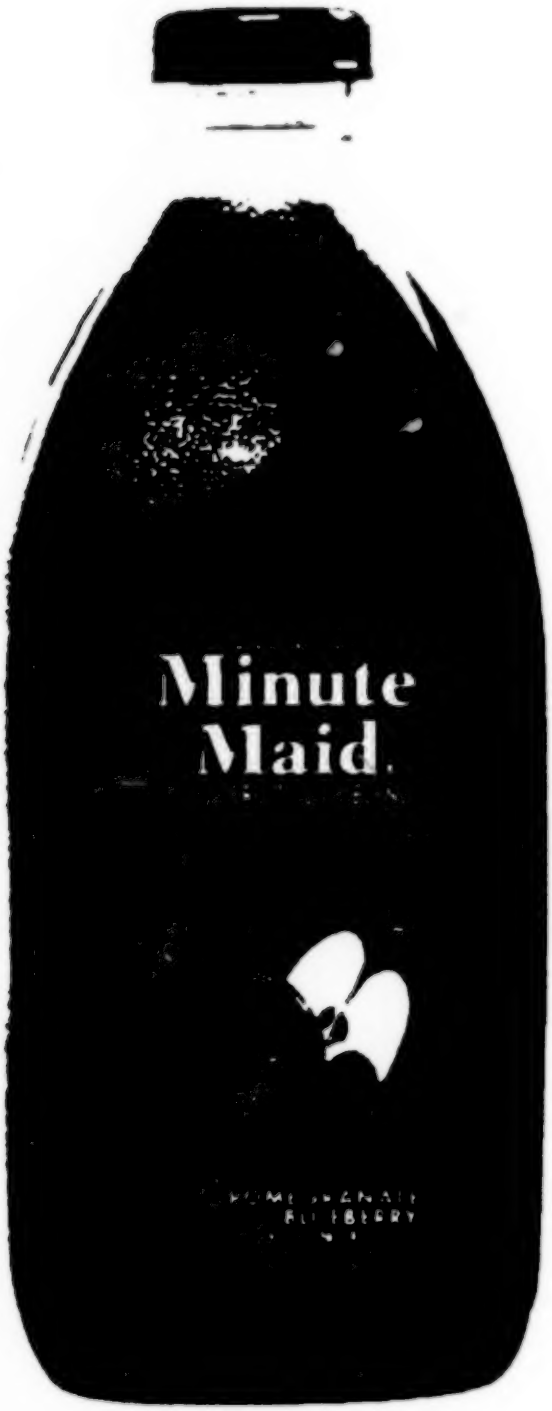
STATEMENT OF THE CASE

1. The Lanham Act creates a private right of action against anyone who uses a "false or misleading" description or representation "in connection with any goods or services" or who, "in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities." 15 U.S.C. § 1125(a). The Act's purpose is to prevent unfair competition. *See id.* § 1127 (noting that the

"intent" of the Lanham Act includes protection "against unfair competition"). In addition to protecting consumers from being misled, the Act protects businesses from unfair competitive acts by providing a private cause of action to a commercial plaintiff that has been harmed by a competitor's false advertising. Any person "who believes that he or she is or is likely to be damaged by" the use of a false description or misrepresentation may bring a lawsuit under the Lanham Act. *Id.* § 1125(a).

The FDCA, in contrast, regulates food and beverage labeling and provides that food is "deemed to be misbranded" in a variety of circumstances. 21 U.S.C. § 343. The statute serves a purpose that is distinct from, but complementary to, the purposes of the Lanham Act: It was enacted to protect public health and safety by ensuring that food and beverages are not misbranded. The FDA has promulgated regulations—relied upon by Coca-Cola for its defense in this action—that address various aspects of food labeling, including labeling of juice products. *See, e.g.*, 21 C.F.R. § 102.33(c)-(d). Only the federal government may enforce the FDCA, 21 U.S.C. § 337(a); the FDCA contains no private cause of action.

2. Pom produces, markets, and sells POM WONDERFUL® brand bottled pomegranate juice and various pomegranate juice blends, including a pomegranate blueberry juice blend. App. 1a. Coca-Cola markets and sells bottled juices and juice blends under the Minute Maid brand. *Id.* In September 2007, Coca-Cola announced the launch of a new "Pomegranate Blueberry" product. *Id.* An image of the front label of Coca-Cola's product is set forth below.


Minute
Maid.

The product's emphasis on pomegranate and blueberry juice is unmistakable—the name "Pomegranate Blueberry" appears in large font with the words "Flavored Blend of 5 Juices" appearing only in smaller font below the name; the vignette on the bottle displays a pomegranate and blueberries as prominently as an apple and grapes; and the juice inside the bottle is artificially colored a deep purple that resembles the color of pomegranate juice. Yet Coca-Cola's "Pomegranate Blueberry" product contains only 0.3% pomegranate juice and 0.2% blueberry juice; it consists primarily of (less expensive and less desirable) apple and grape juices, which amount to over 99% of the juice. App. 2a. Nowhere on Coca-Cola's label are these percentages disclosed.

Unsurprisingly, Coca-Cola's "Pomegranate Blueberry" product is, in fact, misleading to consumers. A consumer survey revealed that

> a substantial proportion of potential purchasers of pomegranate and blueberry juice blends are likely to mistakenly believe that [Coca-Cola's juice] mainly contains pomegranate and blueberry juice (and not other types of fruit juice) due to the packaging (the words "pomegranate blueberry" on the front of the bottle and in the product name on the back of the bottle).

App. 32a-33a (quoting survey report) (internal quotation marks omitted). Indeed, 36% of consumers that were shown the juice's bottle label believed that the juice contains mainly pomegranate and blueberry juice. *See id.* n.8.

Coca-Cola "has received a record number of complaints" regarding its "Pomegranate Blueberry" product. App. 31a. A 14-year employee of Coca-Cola who

has "field[ed] consumer complaints about many products" admitted that "there have been no Minute Maid products about which consumers have complained more." *Id.* (internal quotation marks omitted). One such consumer, for example, complained:

> Today I made the mistake of buying [the] Minute Maid product that you call "Pomegranate Blueberry[.]" What a crock. It's nothing but fancy apple grape juice. You people are scumbags for mislabeling your products. I'll never buy this product again. I'll never buy Minute Maid products again. And I'll tell all of my friends about this fraud. Thanks for wasting my time and money[.]

Id. 31a-32a (alterations and omission in original) (footnote omitted).

None of this should have surprised Coca-Cola. Prior to the launch of its "Pomegranate Blueberry" product, Coca-Cola's Director of Scientific and Regulatory Affairs sent an internal email stating:

> As discussed here is a copy of the front label for the new MM Enhanced Juice Pomegran[a]te Blueberry product. The product has a blend of apple, grape, pomegranate, blueberry & raspberry juices from conc. We are in compliance with the FDA regs related to the naming of juice containing products. *There is a risk from a misleading standpoint as the product has less than 0.5% of pomegranate and blueberry juices.* [The President and General Manager of Minute Maid] is aware of this issue & is willing to assume the risk.

App. 34a-35a (emphasis added).

3. In September 2008, Pom sued Coca-Cola under the Lanham Act and California law, alleging that Coca-Cola's labeling, marketing, and advertising misled consumers to believe that Coca-Cola's "Pomegranate Blueberry" product consists primarily of pomegranate and blueberry juices, when in fact it consists almost entirely of the less expensive apple and grape juices. App. 3a.

Coca-Cola moved to dismiss Pom's Lanham Act suit on the ground that Coca-Cola's label complied with juice-naming regulations the FDA promulgated under the FDCA, which permit a beverage to be named after a non-predominant juice in certain circumstances. The district court partially granted Coca-Cola's motion to dismiss. App. 83a. The court concluded that Pom's Lanham Act challenge to the name and label of Coca-Cola's "Pomegranate Blueberry" product was barred because Pom's claim "may be construed as impermissibly challenging" the FDA juice-naming regulations. *Id.* 90a. Pom subsequently filed a First Amended Complaint, and, after the district court denied Coca-Cola's subsequent motion to dismiss, the parties conducted discovery. *Id.* 37a, 75a-81a.

The parties then cross-moved for summary judgment. App. 37a. The district court granted partial summary judgment to Coca-Cola, finding that Pom's Lanham Act challenge to Coca-Cola's label was barred by the FDA's regulations because the label "sufficiently comports with the requirements" of those regulations and because any determination with respect to the effect of that labeling should be made by the FDA. *Id.* 62a. Pom appealed the district court's rejection of its challenges to the label.

The Court of Appeals for the Ninth Circuit affirmed, holding that "the FDCA and its regulations bar pursuit of" Pom's Lanham Act claims. App. 9a. The court initially suggested that the suit was barred because "as best [the court] can tell, FDA regulations authorize the name Coca-Cola has chosen." *Id.* Thus, the court of appeals surmised that Pom's challenge "would require [the court] to undermine the FDA's apparent determination that so naming the product is not misleading." *Id.*

But the court of appeals then shifted course, indicating that it did "not suggest that mere compliance with the FDCA or with FDA regulations will always (or will even generally) insulate a defendant from Lanham Act liability." App. 12a. It explained instead: "We are primarily guided in our decision not by Coca-Cola's apparent compliance with FDA regulations but by Congress's decision to entrust matters of juice beverage labeling to the FDA and by the FDA's comprehensive regulation of that labeling." *Id.* The court of appeals concluded that the FDA had sole authority to prevent deceptive labeling: "If the FDA believes that more should be done to prevent deception, or that Coca-Cola's label misleads consumers, it can act." *Id.* 11a.

The court of appeals reached its conclusion that the FDCA barred Pom's Lanham Act claim without identifying a single provision of the FDCA that purports to displace the Lanham Act or even conflicts with it. The court did not cite or adhere to precedents of this Court mandating that potentially competing federal statutes both be given effect absent an irreconcilable conflict between them. Nor did the court identify any basis for distinguishing this Court's decision in *Wyeth*.

Pom petitioned for rehearing and rehearing en banc on June 29, 2012. The Ninth Circuit denied the petition on August 8, 2012.

REASONS FOR GRANTING THE WRIT

I. THE NINTH CIRCUIT'S DECISION CONFLICTS WITH THIS COURT'S PRECEDENTS GOVERNING HOW COURTS SHOULD RECONCILE POTENTIALLY OVERLAPPING FEDERAL STATUTES

The court of appeals' conclusion that the FDCA implicitly displaces the Lanham Act disregards this Court's precedents. The interpretation of a statute "begins with the statutory text, and ends there as well if the text is unambiguous." *BedRoc Ltd., LLC* v. *United States*, 541 U.S. 176, 183 (2004) (plurality). By its plain terms, the Lanham Act applies to Coca-Cola's label and mandates that it not be misleading. Although the Lanham Act contains express exceptions that limit its reach in some circumstances, *see, e.g.*, 15 U.S.C. § 1125(c) (excluding certain trademark dilution claims that "shall not be actionable ... under this subsection"), Congress included no such exception for challenges involving labels regulated in certain respects by the FDA. Similarly, nothing in the FDCA exempts activities that are governed by the FDCA from the Lanham Act's reach. The FDCA sets forth standards with which labels must comply, but it nowhere purports to displace the Lanham Act in all cases involving allegations of misleading juice labeling. Nor do the regulations implementing the FDCA contain any provision barring Lanham Act claims.

Nonetheless, the court of appeals held that "the FDCA and its regulations bar pursuit" of Pom's Lanham Act claim. App. 9a. In reaching that conclusion,

the court of appeals failed to apply this Court's precedents setting forth the standard for determining whether one federal statute implicitly displaces another as well as this Court's guidance in *Wyeth* v. *Levine*, 555 U.S. 555 (2009).

A. The Ninth Circuit Failed To Apply This Court's Irreconcilable Conflict Standard

This Court has repeatedly instructed that courts must give full effect to allegedly competing federal statutes unless they are in "'irreconcilable conflict,' or where the latter Act covers the whole subject of the earlier one and 'is clearly intended as substitute.'" *Branch* v. *Smith*, 538 U.S. 254, 273 (2003) (quoting *Posadas* v. *National City Bank*, 296 U.S. 497, 503 (1936)). When asked to reconcile two federal statutes, courts have a duty to "regard each as effective" if they "are capable of co-existence." *Morton* v. *Mancari*, 417 U.S. 535, 551 (1974). Courts are "not at liberty to pick and choose among congressional enactments." *Id.* Even statutes that "overlap" or may appear to be somewhat "redundan[t]" can be "fully capable of coexisting." *United States* v. *Batchelder*, 442 U.S. 114, 118, 122 (1979).

The Ninth Circuit did not apply this standard and made no effort to reconcile the Lanham Act with the FDCA. Instead, the Ninth Circuit presumed that Coca-Cola's label complies with the FDCA and the FDA's implementing regulations and concluded that this alone precluded federal courts from considering Pom's Lanham Act claim. The court of appeals thus allowed the FDA's mere *authority to regulate* juice labeling to bar application of the Lanham Act to any label falling within that authority. That approach cannot be squared with this Court's precedents.

Had the Ninth Circuit applied this Court's prescribed framework, it would have reached a contrary conclusion. The Lanham Act does not irreconcilably conflict with the FDCA; both statutes can and should be given binding effect.

First, the FDCA and the Lanham Act are "fully capable of coexisting," *Batchelder*, 442 U.S. at 122, because a party generally can comply with both the FDCA's regulation of labeling for health and safety purposes and the Lanham Act's prohibition on misleading advertising. The two statutes can and do coexist because, as this Court has previously explained in a related context, the FDCA merely sets a "floor" for regulation of labels on which other laws can build. *See Wyeth*, 555 U.S. at 577-578. The FDCA requires that a label contain certain information, including "the common or usual name" of the product. 21 U.S.C. § 343(i). FDA regulations specify ways in which this requirement can be satisfied for beverages containing multiple juices. For example, the regulations permit a product containing multiple juices to be labeled using the name of a non-predominant juice so long as the label indicates that the product is a "blend" of juices and is "flavored" with the non-predominant juice. *See* 21 C.F.R. § 102.33(c), (d). Alternatively, the manufacturer may instead indicate on the label the percentage of the drink the non-predominant juice comprises. *Id.* § 102.33(d)(2).

Neither the FDCA nor the FDA's implementing regulations require any of the features Coca-Cola elected to use in its label. They do not *mandate* that Coca-Cola name its product after an ingredient found in only trace amounts and feature that trace ingredient in large font and with a prominent pomegranate graphic on its label. And the regulations certainly do not au-

thorize actual consumer confusion of the type shown by the evidence here, particularly where the defendant knew that it "risk[ed]" misleading consumers but opted "to assume th[at] risk." *See* App. 35a.

Coca-Cola easily could have complied with the FDA's requirements, for example, by declining to emphasize pomegranate and blueberry juice more prominently than the juices making up almost all of the product or disclosing the actual percentage of pomegranate and blueberry juice actually contained in the product. If Coca-Cola had done so, it could have both complied with the FDCA and FDA regulations *and* marketed a product that was not misleading under the Lanham Act. Where, as here, a party can comply with two laws, there is no irreconcilable conflict between those laws. *See, e.g., FTC* v. *A.P.W. Paper Co.*, 328 U.S. 193, 202 (1946).

Second, the Lanham Act and the FDCA have distinct requirements and serve distinct purposes. *Cf. J.E.M. Ag Supply, Inc.* v. *Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 144 (2001) (explaining that when two laws have "different requirements and protections," each should be regarded as effective). The Lanham Act is meant to prevent "unfair competition." 15 U.S.C. § 1127. Its focus is not just on protecting consumers from being misled; it is intended to protect businesses from unfair competitive acts by providing a private cause of action to a commercial plaintiff that has been harmed by a competitor's false advertising. *See Sandoz Pharm. Corp.* v. *Richardson-Vicks, Inc.*, 902 F.2d 222, 230 (3d Cir. 1990).

The FDCA, by contrast, serves a different (though complementary) purpose. It protects public health and safety by ensuring that food and beverages are not

misbranded. *See, e.g.*, *Holk* v. *Snapple Beverage Corp.*, 575 F.3d 329, 331-332 (3d Cir. 2009). The FDCA's food and beverage labeling requirements as amended by the Nutrition Labeling and Education Act ("NLEA"), Pub. L. No. 101-535, 104 Stat. 2353 (1990), require nutritional labeling for most food products and provide ingredient standards for labels. *See Holk*, 575 F.3d at 332. The FDA's regulations further the NLEA's purpose of ensuring that food and beverage labels contain appropriate nutritional information. Congress has not authorized private parties to enforce the FDCA or the FDA's regulations; sole enforcement responsibility lies with the United States. 21 U.S.C. § 337(a).

The FDCA and the Lanham Act are not in conflict. FDA enforcement of the FDCA's public health goals is not undermined by a private plaintiff's effort to prevent unfair competition through the Lanham Act. If anything, the statutes' requirements work in tandem to ensure that labels are marketed in ways that are *both* safe for consumers and not misleading. The statutes complement each other to ensure that consumers have accurate information about food products so that they can make safe, healthy choices. Where, as here, there is no reason that Coca-Cola could not have satisfied both statutes, allowing Pom's Lanham Act suit to proceed does not create an irreconcilable conflict with the FDCA.

B. The Ninth Circuit's Decision Conflicts With This Court's Decision In *Wyeth* v. *Levine*

In *Wyeth* v. *Levine*, 555 U.S. 555 (2009), this Court held that the FDA's approval of a specific warning label placed on a drug was not a defense to state tort failure-to-warn claims against a drug manufacturer alleging that certain information was omitted from the label.

See id. at 558. The Court reviewed the history of federal regulation of drugs and drug labeling in order to discern the "purpose of Congress" in enacting the FDCA. *Id.* at 566. The Court then rejected the petitioner's contention that permitting a state-law cause of action would obstruct the purposes and objectives of the FDCA, finding that this argument relied on "an untenable interpretation of congressional intent and an overbroad view of an agency's power to pre-empt state law." *Id.* at 573. The Court further concluded that "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id.* at 575. "To the contrary, it cast federal labeling standards as a floor upon which States could build and repeatedly disclaimed any attempt to pre-empt failure-to-warn claims." *Id.* at 577-578.

Although *Wyeth* involved preemption, the teachings of *Wyeth* apply with equal force here. *Wyeth*'s reasoning and interpretation of the FDCA's preemptive effect on state law in the drug labeling context guides the analysis of that statute's preclusive effect on other *federal* laws. The conflict preemption standard[1] applied in *Wyeth* asks whether state law "creates an unacceptable 'obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" 555 U.S. at 563-564 (quoting *Hines* v. *Davidowitz*, 312 U.S.

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[1] State-law preemption analysis in the food and beverage labeling context differs from that in *Wyeth* because the FDCA contains an express preemption provision applicable to regulation of food and beverage labeling, *see* 21 U.S.C. § 343-1, and the NLEA provides that the Act "shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [21 U.S.C. § 343-1] of the [FDCA]." Pub. L. No. 101-535 § 6(c), 104 Stat. 2353, 2364 (1990) (21 U.S.C. § 343-1 note).

52, 67 (1941)). For the very same reason state-law failure-to-warn claims do not create an "obstacle" to Congress's purposes and objectives in the FDCA, federal Lanham Act false advertising claims do not create an "irreconcilable conflict" with the FDCA. Just as the FDCA does not set a ceiling that precludes application of state laws in the drug context, it does not preclude application of another federal law in the food and beverage labeling context. In this case, for example, there is no doubt that Coca-Cola could have complied with both the FDCA and the Lanham Act.

In the same way that state laws offer "an additional, and important, layer of consumer protection that complements FDA regulation," *Wyeth*, 555 U.S. at 579, the Lanham Act provides a layer of consumer and competitor protection that the FDCA does not address. The FDA's authority to regulate labeling does not preempt all parallel regimes. *See id.* at 573. As the Third Circuit has recognized, "the FDA has stated that it does not intend to occupy the field of food and beverage labeling, even with regard to regulations affecting juice products." *Holk*, 575 F.3d at 338. And as this Court emphasized in *Wyeth*, it is "manufacturers, not the FDA, [who] bear primary responsibility for their drug labeling at all times." 555 U.S. at 579. Like state-law failure-to-warn claims in the drug context, the Lanham Act "complements FDA regulation," *id.*, by permitting an aggrieved party to bring suit challenging deceptive labeling even where the label might not separately violate the FDA's food and beverage labeling regulations.

The decision below did not address this Court's decision in *Wyeth*. Instead, the Ninth Circuit concluded that Pom's Lanham Act claim was barred simply because the FDA regulates Coca-Cola's label. That is

precisely what this Court declined to do in *Wyeth*. This Court should grant review to correct the Ninth Circuit's failure to adhere to this Court's precedents.

II. THE NINTH CIRCUIT'S DECISION CREATES A CONFLICT AMONG THE COURTS OF APPEALS

Review by this Court is also necessary to address a conflict among the circuits. The Ninth Circuit's decision conflicts with decisions of three different courts of appeals that found false labeling or advertising claims actionable under the Lanham Act notwithstanding federal regulation and that applied a fundamentally different approach to determining whether Lanham Act claims are precluded.

1. The Ninth Circuit's decision conflicts with the Eighth Circuit's decision in *Alpharma, Inc.* v. *Pennfield Oil Co.*, 411 F.3d 934 (8th Cir. 2005). In *Alpharma*, the plaintiff brought suit under the Lanham Act alleging that the defendant falsely advertised that the FDA had approved its product. The defendant argued that the Lanham Act claims were precluded because "Congress did not intend for the Lanham Act to be a vehicle for enforcing the provisions [of the FDCA] indirectly, and the area is within the expertise of the FDA." *Id.* at 939. In rejecting that argument, the Eighth Circuit drew on prior circuit precedent that had "confirmed the viability of Lanham Act claims concerning representations of FDA approval" and held that because the plaintiff's Lanham Act claim did not require a determination by the court of how the FDA would interpret and enforce its own regulations, the FDCA did not bar that claim. *Id.* at 941.

Prior to the decision below, the Ninth Circuit had employed a standard similar to that applied in *Alphar-*

ma. It had held that a Lanham Act claim is foreclosed only when it "would require [the court] to usurp [the FDA's] responsibility for interpreting and enforcing" the FDCA. *PhotoMedex, Inc.* v. *Irwin*, 601 F.3d 919, 930 (9th Cir. 2010) (quoting *Sandoz*, 902 F.2d at 231 (internal quotation marks omitted)). As the Ninth Circuit acknowledged in *PhotoMedex*, however, that rule does not apply where "the claim would *not* require a preemptive interpretation by the court of FDA regulations." 601 F.3d at 929-930 (emphasis added).

In this case, the Ninth Circuit reversed course and ignored this distinction altogether. Pom seeks to enforce its rights under the Lanham Act entirely independent of the FDCA and does not seek to enforce the FDCA at all. Pom's claim does not rely upon the FDCA or FDA regulations to prove that Coca-Cola's label is likely to mislead consumers. To the contrary, as the Lanham Act requires, Pom has tendered independent evidence that Coca-Cola's label is likely to deceive consumers notwithstanding the label's purported compliance with the requirements of the FDCA. *See* App. 30a-35a (discussing Pom's evidence of consumer survey data, consumer complaints, and admissions by Coca-Cola's own senior employees who developed the product). Pom's claim also does not require any judicial interpretations of the FDCA or the FDA's regulations; those regulations are immaterial to Pom's allegations. Yet rather than follow the rule it had previously recognized in *PhotoMedex* and that the Eighth Circuit applied in *Alpharma*, the Ninth Circuit has now precluded *all* Lanham Act claims touching on food and beverage labeling irrespective of whether those claims require interpretation of FDA regulations. *See* App. 12a (finding preclusion based on asserted compliance and "comprehensive regulation").

2. The Ninth Circuit's holding that the FDA's mere regulation of food and beverage labeling bars Pom's Lanham Act claim also conflicts with the Third Circuit's decision in *Sandoz*, 902 F.2d 222, which permitted a Lanham Act challenge to drug advertising to proceed despite overlapping federal regulation and foreclosed the plaintiff's Lanham Act challenge to the drug's label only because it would have required the court to interpret and enforce regulations promulgated by the FDA. The Third Circuit first considered what a plaintiff needs to show when raising a false advertising claim under the Lanham Act. The court concluded that a plaintiff cannot meet its burden under the Lanham Act simply by demonstrating that the defendant's advertising claims about a drug's effectiveness "are inadequately substantiated under FDA guidelines." *Id.* at 229. Instead, "the plaintiff must *also* show that the claims are literally false or misleading to the public." *Id.* (emphasis added). The court thus permitted the Lanham Act false advertising claim to proceed despite the authority of the FDA and the Federal Trade Commission to regulate the advertising because—like Pom's claim here—it did not implicate the relevant regulations. By contrast, the *Sandoz* court held that the plaintiff's labeling claim—which (unlike Pom's claim) expressly turned on the definition of the term "active ingredient" set forth in an FDA regulation—was barred because that claim would have required the court to "usurp" the FDA's responsibility for "interpreting and enforcing potentially ambiguous regulations." *Id.* at 231.

The Ninth Circuit's decision cannot be reconciled with either of *Sandoz*'s holdings. *Sandoz*'s first holding—requiring a private party suing under the Lanham Act to show more than mere noncompliance with

FDA's rules—necessarily means that mere federal regulatory authority does not preclude a Lanham Act claim altogether. If, as the Ninth Circuit held here, agency regulation precluded any private cause of action against a regulated defendant, then the Third Circuit's holding that a plaintiff must prove more than mere noncompliance with FDA guidelines would have been entirely unnecessary. The very fact that there were regulations with which the defendant was supposed to comply would have precluded the action altogether. The second holding of *Sandoz*—finding a Lanham Act challenge to a drug label barred because it would have required the court to interpret and enforce the FDCA—also conflicts with the decision of the court below. The court of appeals here foreclosed Pom's Lanham Act claim without considering whether it would have required interpretation of or was an attempt to enforce the FDA's regulations.

The resulting conflict means that in the Third Circuit, a Lanham Act plaintiff may bring a lawsuit that challenges a product governed by agency regulations, so long as (1) he proves "that the claims are literally false or misleading to the public," and (2) the claim does not require "original interpretation" of those regulations. *Sandoz*, 402 F.2d at 229-231. But in the Ninth Circuit, the mere fact that the product is subject to federal agency regulation would provide a defense to that very same lawsuit. Pom's claim, which was entirely independent of the FDCA and FDA regulations, would be permitted in the Third Circuit, but was barred in the Ninth Circuit.

3. Like the Eighth and the Third Circuits, the Tenth Circuit has also held—in conflict with the decision of the Ninth Circuit here—that false labeling challenges under the Lanham Act are actionable even if a

product is regulated by a federal enforcement agency. In *Cottrell, Ltd.* v. *Biotrol Intern., Inc.*, 191 F.3d 1248 (10th Cir. 1999), the court addressed a Lanham Act claim alleging that the defendants misleadingly represented that their hard surface cleaner had obtained clearance from the Environmental Protection Agency ("EPA"). *Id.* at 1250. The defendants argued that the plaintiff could not pursue its Lanham Act claim because the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") "is the exclusive federal law that regulates the labeling of pesticides." *Id.* at 1253. The Tenth Circuit rejected the defendants' argument, finding that the plaintiff could bring its Lanham Act suit because the plaintiff was "not attempting to enforce FIFRA, but rather to vindicate its rights under the Lanham Act *independent of FIFRA*." *Id.* at 1254 (emphasis added).

The Tenth Circuit looked to cases that considered the Lanham Act's relationship to the FDCA, finding them applicable to *Cottrell* because "the EPA stands in a similar enforcement relationship to FIFRA as the FDA does to the FDCA." 191 F.3d at 1255. The court gleaned from these cases the very proposition that the Ninth Circuit rejected here: "Affirmative misrepresentations ... are generally actionable under the Lanham Act, *even if the product is regulated by the FDA*." *Id.* at 1254 (quoting *Braintree Labs., Inc.* v. *Nephro-Tech, Inc.*, No. 96-2459, 1997 WL 94237 (D. Kan. Feb. 26, 1997) (emphasis added)). The Tenth Circuit noted that the defendants "would have [the court] dismiss this case because [the plaintiff]'s Lanham Act claim touches on issues covered by FIFRA." *Id.* at 1256. Unlike the Ninth Circuit, the Tenth Circuit rejected that idea: "[B]ecause FIFRA nowhere explicitly precludes Lanham Act coverage, we refuse to limit the scope of the Lanham Act absent circumstances that inherently re-

quire interpretation of FIFRA regulations and/or EPA approvals." *Id.*

As explained above, Pom's claim did not require the court of appeals to interpret the FDCA or the FDA's implementing regulations. Yet the Ninth Circuit dismissed that claim simply because it "touche[d] on issues" covered by those regulations. *See* App. 12a ("Out of respect for the statutory and regulatory scheme before us, we decline to allow the FDA's judgments to be disturbed."). In so doing, the Ninth Circuit has parted ways with its sister circuits, creating an untenable conflict among the courts of appeals that only this Court can reconcile.

III. The Question Presented Is Important

This case involves an issue of significant importance with far-reaching implications. The court of appeals' decision would eliminate suits by private parties under the Lanham Act challenging the truthfulness of food and beverage labeling. The job of policing false labeling thus would be left to the FDA. The agency, however, is in no position to address the problem of false and misleading labeling on its own.

The FDA is charged with a number of critical missions. According to the agency, it is responsible for:

- Protecting the public health by assuring that foods are safe, wholesome, sanitary and properly labeled; human and veterinary drugs, and vaccines and other biological products and medical devices intended for human use are safe and effective
- Protecting the public from electronic product radiation

- Assuring cosmetics and dietary supplements are safe and properly labeled
- Regulating tobacco products
- Advancing the public health by helping to speed product innovations
- Helping the public get the accurate science-based information they need to use medicines, devices, and foods to improve their health[2]

As Congress has long understood, the FDA woefully lacks the resources necessary to perform each of these functions adequately. In *Wyeth*, this Court noted that the "FDA has limited resources" to conduct even what might be its most critical mission: to ensure the safety and effectiveness of pharmaceuticals. 555 U.S. at 578. For this reason, even in that area of significant scientific complexity, the FDA has "long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation." *Id.* at 579.

In the area of food and beverage labeling, the agency's resources are even more markedly inadequate to its mission. In 2008, the GAO published a comprehensive analysis of the FDA's efforts to regulate food labeling. *See* U.S. Gov't Accountability Office, GAO 08-597, *Food Labeling: FDA Needs to Better Leverage Resources, Improve Oversight, and Effectively Use Available Data to Help Consumers Select Healthy Foods* (2008) ("GAO Report"), *available at* http://www.gao.gov/

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[2] U.S. Food and Drug Administration, *What does FDA do?*, http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194877.htm.

assets/290/280466.pdf. The Report's overall conclusion was summarized as follows: "FDA has limited assurance that domestic and imported foods comply with food labeling requirements, such as those prohibiting false or misleading labeling." *Id.* at 5.

More specifically, the Report explained that: "FDA has reported that limited resources and authorities significantly challenge its efforts to carry out food safety responsibilities—challenges that also impact efforts to administer and enforce labeling requirements." GAO Report 6. In 2007, over 65,000 firms were subject to FDA's food regulations. *See id.* at 51. These firms, of course, manufacture countless numbers of different food products. But from 2005 to 2007, the portion of the FDA Office of Nutrition, Labeling, and Dietary Supplements "dedicated to food labeling activities" had an annual budget of only "$1.1 million to $1.3 million" and had only "from 9.0 to 10.5" full-time equivalent employees. *Id.* at 7. From 1998 through 2006, FDA obtained only *two* injunctions against firms for mislabeling. *See id.* at 22. For the most part, the agency simply issued warning letters. *See id.* at 18-21.

FDA has acknowledged that it generally does not even attempt to police misleading food labels:

> [A]ccording to FDA officials, the agency generally does not address misleading food labeling because it lacks the resources to conduct the substantive, empirical research on consumer perceptions that it believes it would need to legally demonstrate that a label is misleading ....

GAO Report 30.

Because the FDA lacks the resources effectively to regulate false labeling, the Ninth Circuit's decision pre-

cluding private parties from challenging food labels under the Lanham Act will have the practical effect of leaving food labels almost entirely unregulated.[3] There is no indication that Congress intended that extraordinary result.

The unbounded scope of the court of appeals' decision only magnifies its adverse impact. Under the Ninth Circuit's ruling, so long as products meet the FDA's minimum requirements, manufacturers can label them in any manner, without regard to whether their labeling deceives consumers. The ruling displaces even Lanham Act claims that allege that a manufacturer has *knowingly* used a label that is misleading. For example, in this case, Pom pointed to evidence that Coca-Cola knew that there was "a risk from a misleading standpoint as the product has less than 0.5% of pomegranate and blueberry juices" but was "willing to assume the risk." App. 35a.

The Ninth Circuit's holding also reaches beyond food and beverage labeling potentially to any claim under the Lanham Act that targets a product regulated by the FDA or, indeed, other agencies. One court has already applied the Ninth Circuit's decision to preclude a Lanham Act claim challenging the labeling of personal care and cosmetic products as "organic" in light of the USDA's regulation of such products under the Organic Food Products Act of 1990. *See All One God Faith, Inc.* v. *Hain Celestial Grp., Inc.*, No. 09-3517,

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[3] Indeed, if taken to its logical extreme, the court of appeals' apparent conclusion that compliance with particular juice-naming regulations precludes a juice label from being misleading (*see* App. 9a-12a) might impair even the FDA's authority to take action against misleading labels.

2012 WL 3257660, at *1-11 (N.D. Cal. Aug. 8, 2012). And the reasoning of the Ninth Circuit's decision extends beyond the Lanham Act to other areas in which the federal government has regulatory authority but private parties are permitted to bring civil actions. A broad range of federal statutes afford individuals a private right of action while also providing for government enforcement. *See, e.g.*, 29 U.S.C. § 2617 (Family Medical Leave Act of 1993 ("FMLA")) (creating a private right of action "against any employer" who "interfere[s] with, restrain[s], or den[ies] the exercise of" FMLA rights); 15 U.S.C. § 26 (Clayton Act) (providing a private right of action "against threatened loss or damage by a violation of the antitrust laws"). The Ninth Circuit's reasoning in this case threatens the viability of such dual-enforcement regimes.

CONCLUSION

For the foregoing reasons, the Court should grant Pom's petition for a writ of certiorari.

Respectfully submitted.

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DECEMBER 2012

APPENDIX

APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

POM WONDERFUL LLC, a Delaware limited liability company,
Plaintiff-Appellant,

v.

THE COCA-COLA COMPANY, a Delaware corporation,
Defendant-Appellee.

No. 10-55861
Argued and Submitted Feb. 8, 2012
Filed May 17, 2012

OPINION

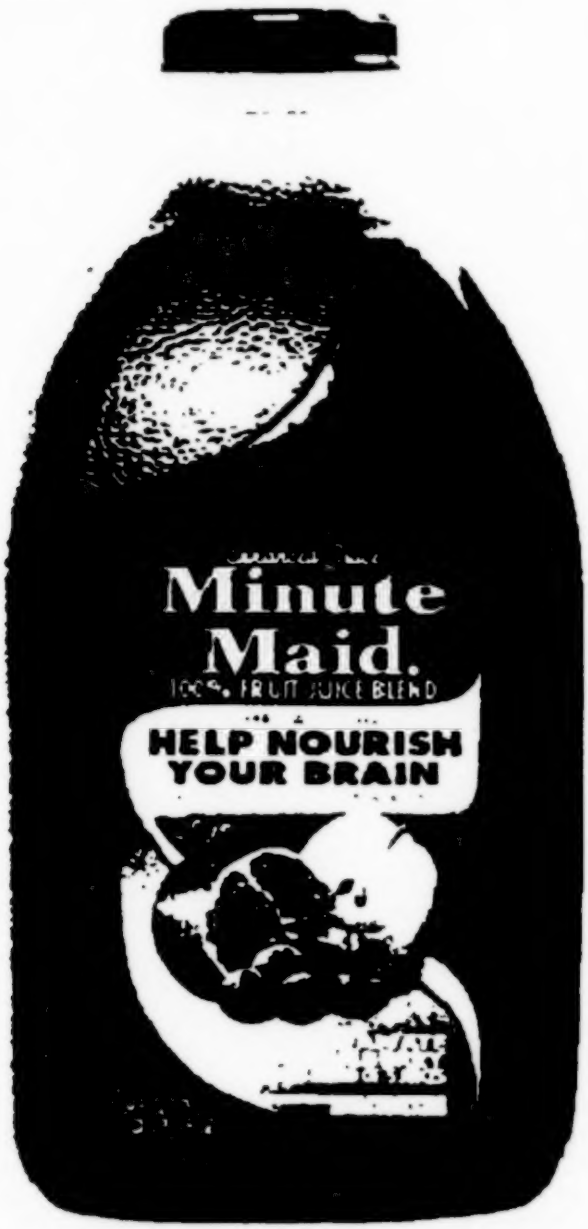
O'SCANNLAIN, Circuit Judge:

We must decide whether the Food, Drug, and Cosmetic Act bars a Lanham Act claim alleging that the name and labeling of a juice beverage are deceptive.

I

Pom Wonderful LLC produces, markets, and sells bottled pomegranate juice and pomegranate juice blends, including a pomegranate blueberry juice blend. The Coca-Cola Company markets and sells bottled juices and juice blends under the Minute Maid brand. In September 2007, Coca-Cola announced a new product called "Pomegranate Blueberry" or "Pomegranate Blueberry Flavored Blend of 5 Juices." (The parties

dispute the name. We at times refer to Coca-Cola's product as "Pomegranate Blueberry" but take no view on whether this is its actual name.) This product contains about 99.4% apple and grape juices, 0.3% pomegranate juice, 0.2% blueberry juice, and 0.1% raspberry juice. The front label displays the product's name and a vignette depicting each of those fruits:



Believing that it was losing sales to Pomegranate Blueberry, Pom sued Coca-Cola in September 2008. Pom alleged that Coca-Cola misled consumers to believe that Pomegranate Blueberry consists primarily of pomegranate and blueberry juices when it actually consists mainly of (the cheaper) apple and grape juices. Pom challenged the name, labeling, marketing, and advertising of Pomegranate Blueberry. It claimed that Coca-Cola violated the false-advertising provision of the Lanham Act, which authorizes suit against those who use a false or misleading description or representation about any goods. *See* 15 U.S.C. § 1125(a). Pom also claimed that Coca-Cola violated California's Unfair Competition Law (UCL) and its False Advertising Law (FAL), which prohibit deceptive practices and misleading advertising. *See* Cal. Bus. & Prof'l Code § 17200 *et seq.*; *id.* § 17500 *et seq.*

Coca-Cola moved under Federal Rule of Civil Procedure 12(b)(6) to dismiss the complaint for failure to state a claim. The district court partially granted and partially denied the motion. The court ruled that Pom's Lanham Act challenge to Pomegranate Blueberry's name and labeling was barred because Pom's suit "may be construed as impermissibly challenging" Food and Drug Administration (FDA) regulations permitting the name and labeling that Coca-Cola uses and because Pom's claim could improperly require the court to interpret and to apply FDA regulations on juice beverage labeling. But the court also held that Pom's Lanham Act challenge could otherwise proceed. Specifically, the court ruled that, although Pom could not challenge Pomegranate Blueberry's name and labeling, it could challenge Coca-Cola's other advertising and marketing of the product because those components of the claim would not require the court to interpret FDA

regulations. The court also held that the Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, expressly preempted Pom's state law claims to the extent the UCL and FAL impose obligations that are not identical to those imposed by the FDCA and its implementing regulations.

After Coca-Cola refused to respond to discovery requests, Pom amended its complaint to bring itself within the scope of the court's earlier ruling on its Lanham Act claim. The amended complaint repleaded Pom's Lanham Act, UCL, and FAL claims. In an apparent effort to overcome the court's preemption ruling, Pom added to its UCL claim a misbranding allegation under California's Sherman Law, which includes language that is materially identical to the FDCA's misbranding provision. *See* Cal. Health & Safety Code § 110660; *compare id. with* 21 U.S.C. § 343(a)(1).

Coca-Cola moved under Rule 12(b)(6) to dismiss the amended complaint. The court denied Coca-Cola's motion and ruled that Pom could conduct discovery to clarify which aspects of Coca-Cola's alleged conduct constituted labeling (and thus could not, under the court's earlier ruling, support Pom's Lanham Act claim) and which aspects constituted advertising or marketing (and thus could support the Lanham Act claim). The court did not address preemption. Discovery followed.

When discovery was completed, the district court partially granted summary judgment to Coca-Cola. The court reiterated that Pom's Lanham Act challenge to Pomegranate Blueberry's name and labeling was barred by the FDCA's implementing regulations. The court reasoned that through its regulations, the FDA "has directly spoken on the issues that form the basis of Pom's Lanham Act claim against the naming and label-

ing of the Juice, and has therefore[] reached a conclusion as to what is permissible." The court emphasized that the FDA "has concluded that manufacturers of multiple-juice beverages may identify their beverages with a non-primary, characteristic juice, as Coca[-]Cola does here." Because in its view Coca-Cola's label "sufficiently comports with the requirements of" FDA juice-labeling regulations—and because it believed that any further "determination that naming and labeling must be displayed in a particular way or fashion" must be made by the FDA—the court held that Pom's claim challenging the name and labeling of Pomegranate Blueberry was barred. The court reached a similar conclusion specifically about the label's fruit vignette.

The court did not revisit its earlier preemption ruling. It simply ruled that Pom lacked statutory standing to pursue its state law claims. The court reasoned that Pom had not established the statutory standing prerequisite of "lost money or property," Cal. Bus. & Prof'l Code §§ 17204, 17535, because Pom had not shown that it was entitled to restitution.

The court concluded that triable issues remained on the non-naming-and-labeling aspects of Pom's Lanham Act claim and permitted Pom to proceed to trial on those matters. But Pom conceded that the summary judgment order prevented it from carrying its burden on the claim and the court therefore entered judgment for Coca-Cola. Pom timely appealed.

II

On appeal, Pom contends that the district court erred in its holdings that the FDCA bars its Lanham Act claim, that Pom lacks statutory standing to pursue its state law claims, and that the FDCA expressly

preempts Pom's state law claims against the name and labeling of Coca-Cola's Pomegranate Blueberry.

A

The Lanham Act broadly prohibits false advertising. It authorizes suit against those who use a false or misleading description or representation "in connection with any goods." 15 U.S.C. § 1125(a). Such suits can be brought by any person "who believes that he or she is or is likely to be damaged by" the use of that false description or representation. *Id.*

The FDCA, meanwhile, comprehensively regulates food and beverage labeling. It provides that a food is misbranded if "its labeling is false or misleading in any particular," 21 U.S.C. § 343(a)(1), or "[i]f any word, statement, or other information required by" the FDCA or its regulations "to appear on the label or labeling is not prominently placed thereon with such conspicuousness ... and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use," *id.* § 343(f). Though a private plaintiff may sue under the Lanham Act's false-advertising provision, the FDCA may be enforced only by the FDA or the Department of Justice. *See id.* § 337(a). The FDA, for its part, has promulgated regulations that address how a manufacturer may name and label its juice beverages. *See, e.g.*, 21 C.F.R. § 102.33(c), (d).

As sometimes happens with two broad federal statutes, the Lanham Act and the FDCA can conflict with each other. When faced with a potential conflict, "[c]ourts try to give as much effect to both statutes as possible." *Schering-Plough Healthcare Prods., Inc. v. Schwarz Pharma, Inc.*, 586 F.3d 500, 508 (7th Cir. 2009). In that effort, courts have focused on Congress's

decision to entrust to the FDA the task of interpreting and enforcing the FDCA.

In light of that focus, courts have agreed that the FDCA limits claims under the Lanham Act. A plaintiff may not, for example, sue under the Lanham Act to enforce the FDCA or its regulations because allowing such a suit would undermine Congress's decision to limit enforcement of the FDCA to the federal government. *See, e.g., Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993). Nor may a plaintiff maintain a Lanham Act claim that would require a court originally to interpret ambiguous FDA regulations, because rendering such an interpretation would usurp the FDA's interpretive authority. *See, e.g., Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231-32 (3d Cir. 1990) (claim that drug label falsely described ingredient as "inactive" was barred because FDA had not decided whether ingredient was active or inactive).

Where the FDA has not concluded that particular conduct violates the FDCA, we have even held that a Lanham Act claim may not be pursued if the claim would require litigating whether that conduct violates the FDCA. *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 924 (9th Cir. 2010). In PhotoMedex, a manufacturer of a dermatological laser alleged that its competitor violated the Lanham Act by misrepresenting that its product had been "cleared" (approved) by the FDA. The FDCA allows a manufacturer to market such a laser only if the FDA has cleared the device or a similar device. *Id.* at 925-26. But the FDCA and FDA regulations permit a manufacturer to determine in the first instance whether its device is covered by an earlier clearance and to market the device even if the FDA has not stated that the device is cleared. *See id.* at 922, 925-26, 928. In keeping with the statute and regulations,

the defendants in PhotoMedex represented that their device had been cleared based on the FDA's approval of a similar device. The FDA had not weighed in on whether that representation was accurate. We held that the plaintiff's Lanham Act claim against that representation was barred. Recognizing that the claim would have required us to "[t]est[] the truth" of the defendants' clearance statement, we refused "to usurp the FDA's prerogative to enforce the FDCA" by deciding whether the defendants' device was covered by the FDA's earlier clearance of a different device. *Id.* at 928.

PhotoMedex teaches that the Lanham Act may not be used as a vehicle to usurp, preempt, or undermine FDA authority. That teaching, however, operates as a presumption or a general principle—not as an automatic trump or a firm rule. Our task in cases involving potentially conflicting statutes is "to give as much effect to both statutes as possible." *Schering-Plough*, 586 F.3d at 508. To do that, a court must focus on the circumstances before it to strike a balance that disrupts the two statutory schemes as little as it can. Thus, in *PhotoMedex*, while we resolved not "to usurp the FDA's prerogative" to enforce the FDCA or to apply its own regulations, 601 F.3d at 928, we grounded that resolution in "the particular circumstances of th[e] case," *id.* at 922: the authority Congress entrusted to the FDA, the regulatory regime put in place by the FDA, the FDA's actions relevant to the plaintiff's claim, and other similar factors, *id.* at 922, 925-28. In this case we must again focus on the circumstances before us to strike the right balance.

B

Applying the teaching of *PhotoMedex* to the circumstances of this case, we conclude that the FDCA and its regulations bar pursuit of both the name and labeling aspects of Pom's Lanham Act claim.

The naming component of Pom's claim is barred because, as best we can tell, FDA regulations authorize the name Coca-Cola has chosen. The FDA has concluded that a manufacturer may name a beverage using the name of a flavoring juice that is not predominant by volume. *See* 21 C.F.R. § 102.33(c), (d). Section 102.33(c) recognizes, for example, that a blend of juices can represent a juice in its name or label even if the blend "also contains a juice other than the ... juice" named or represented on the label. And the FDA has explained, by way of example, that a three-juice blend where apple is the juice identified on the label can be named "Apple blend; apple juice in a blend of two other fruit juices." *Id.* § 102.33(c) (internal quotation marks omitted). The FDA has also said that a "named" juice need "not [be] the predominant juice" by volume. *Id.* § 102.33(d). Thus a raspberry-and-cranberry-flavored product whose predominant juice is not raspberry or cranberry can be called " 'Raspcranberry'; raspberry and cranberry flavored juice drink." *Id.* § 102.33(d)(1). Taken together, these provisions reflect that: (1) Coca-Cola may give its product a name that refers to juices that provide the characterizing flavor, and (2) those juices need not be predominant by volume if Coca-Cola states that those juices are not predominant. Thus, Pom's challenge to the name "Pomegranate Blueberry Flavored Blend of 5 Juices" would create a conflict with FDA regulations and would require us to undermine the FDA's apparent determination that so naming the product is not misleading. *Cf. PhotoMedex*, 601 F.3d at

928. The district court was right to hold that Pom's Lanham Act claim against Pomegranate Blueberry's name is barred.

The same goes for the labeling component of Pom's claim. Pom focuses its labeling argument on how Coca-Cola presents the words "Pomegranate Blueberry" and "Flavored Blend of 5 Juices" on the product's label. (Pom does not meaningfully contend, on appeal, that the label's fruit vignette—which depicts all of the fruits of which the product is composed—is improper.) Pom apparently wants to force Coca-Cola to alter the size of the words on its labeling so that the words "Pomegranate Blueberry" no longer appear in larger, more conspicuous type on Coca-Cola's label than do the words "Flavored Blend of 5 Juices." But allowing Pom to achieve this result would again undermine the FDA's regulations and expert judgments. In extensively regulating the labeling of foods and beverages, the FDCA and its implementing regulations have identified the words and statements that must or may be included on labeling and have specified how prominently and conspicuously those words and statements must appear. *See, e.g.*, 21 U.S.C. § 343(f), (i); 21 C.F.R. § 102.33(c), (d). These provisions ensure that statements are presented on labels in such a way "as to render [them] likely to be read and understood by the ordinary individual." 21 U.S.C. § 343(f).

Congress and the FDA have thus considered and spoken to what content a label must bear, and the relative sizes in which the label must bear it, so as not to deceive. Despite speaking extensively to how prominently required words or statements must appear, the FDA has not (so far as we can tell) required that all words in a juice blend's name appear on the label in the same size or that words hew to some other standard

that Pom might have us impose. If the FDA thought such a regulation were necessary "to render [that information] likely to be read and understood by the ordinary individual," 21 U.S.C. § 343(f), it could have said so. If the FDA believes that more should be done to prevent deception, or that Coca-Cola's label misleads consumers, it can act. But, under our precedent, for a court to act when the FDA has not—despite regulating extensively in this area—would risk undercutting the FDA's expert judgments and authority.

Pom urges us to follow three district courts that concluded that similar Lanham Act claims brought by Pom may proceed because those claims did not require the court to interpret or to apply FDA regulations. *See Pom Wonderful, LLC v. Tropicana Prods., Inc.*, 2010 WL 3590162, at *1-*2 (C.D. Cal. Sept. 7, 2010); *Pom Wonderful LLC v. Ocean Spray Cranberries, Inc.*, 642 F. Supp. 2d 1112, 1119-20 (C.D. Cal. 2009); *Pom Wonderful LLC v. Welch Foods, Inc.*, CV 09-567 AHM, D.E. 29, at 6-7 (C.D. Cal. June 23, 2009). These decisions cannot be harmonized with *PhotoMedex*. Although these courts were right to recognize that a Lanham Act claim is barred when it would require a court to interpret ambiguous FDA regulations, that is not the only circumstance in which such a claim is barred. *PhotoMedex* teaches that courts must generally prevent private parties from undermining, through private litigation, the FDA's considered judgments.

In concluding that Pom's claim is barred, we do not hold that Coca-Cola's label is non-deceptive. Pom contends that the words "Pomegranate Blueberry" appear in larger, more conspicuous type on Coca-Cola's label than do the words "Flavored Blend of 5 Juices." If the FDA believes that this context misleads consumers, it can act. But the FDA has apparently not taken a view

on whether Coca-Cola's labeling misleads consumers—even though it has acted extensively and carefully in this field. (The FDA has not established a general mechanism to review juice beverage labels before they reach consumers, but the agency may act if it believes that a label in the market is deceptive.) As best we can tell, Coca-Cola's label abides by the requirements the FDA has established. We therefore accept that Coca-Cola's label presumptively complies with the relevant FDA regulations and thus accords with the judgments the FDA has so far made. Out of respect for the statutory and regulatory scheme before us, we decline to allow the FDA's judgments to be disturbed.

We do not suggest that mere compliance with the FDCA or with FDA regulations will always (or will even generally) insulate a defendant from Lanham Act liability. We are primarily guided in our decision not by Coca-Cola's apparent compliance with FDA regulations but by Congress's decision to entrust matters of juice beverage labeling to the FDA and by the FDA's comprehensive regulation of that labeling. To give as much effect to Congress's will as possible, we must respect the FDA's apparent decision not to impose the requirements urged by Pom. And we must keep in mind that we lack the FDA's expertise in guarding against deception in the context of juice beverage labeling. In the circumstances here, "the appropriate forum for [Pom's] complaints is the [FDA]." *PhotoMedex*, 601 F.3d at 929.

III

Which brings us to the question of whether Pom's state law claims may proceed.

To have standing to bring a claim under the UCL, a private plaintiff must show that it "has suffered injury

in fact and has lost money or property as a result of" unfair competition; to have standing under the FAL, a private plaintiff must make the same showing of injury and loss as a result of an FAL violation. Cal. Bus. & Prof'l Code §§ 17204, 17535. The district court interpreted the "lost money or property" language to require a plaintiff to show that it is entitled to restitution from the defendant—even if the plaintiff seeks only injunctive relief. That was error. The California Supreme Court has now made clear that standing under section 17204 (the UCL standing provision) does not depend on eligibility for restitution. *See Kwikset Corp. v. Superior Ct.*, 51 Cal. 4th 310, 120 Cal. Rptr. 3d 741, 246 P.3d 877, 895 (2011); *Clayworth v. Pfizer, Inc.*, 49 Cal. 4th 758, 111 Cal. Rptr. 3d 666, 233 P.3d 1066, 1088 (2010). We are inclined to interpret the materially identical language in section 17535 (the FAL standing provision) the same way. Nevertheless, because these cases came down after the district court entered judgment in this case, we will vacate the judgment as to Pom's state law claims and remand to the district court to rule on standing in light of *Kwikset* and *Clayworth*.

If the district court concludes that Pom has statutory standing, it may need to address such issues as whether Pom's state law claims are expressly preempted and whether California's safe-harbor doctrine insulates Coca-Cola from liability on any of Pom's state law claims. We leave those matters to the district court to address as needed.

IV

To summarize: We affirm the district court's summary judgment to the extent it barred Pom's Lanham Act claim with respect to Pomegranate Blueberry's name and labeling. We vacate the summary judgment

to the extent it ruled that Pom lacked statutory standing on its UCL and FAL claims; we remand so that the district court can rule on the state claims in accordance with this opinion.

AFFIRMED IN PART, VACATED IN PART, AND REMANDED. Each party shall bear its own costs.

APPENDIX B

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

POM WONDERFUL LLC, a Delaware
limited liability company,
Plaintiff-Appellant,

v.

THE COCA COLA COMPANY,
a Delaware corporation,
Defendant-Appellee.

[STAMP: FILED
AUG 08 2012
MOLLY C. DWYER, CLERK
U.S. COURT OF APPEALS]

No. 10-55861

D.C. No. 2:08-cv-06237-SJO-FMO
Central District of California, Los Angeles

ORDER

Before: D.W. NELSON, O'SCANNLAIN, and N.R. SMITH, Circuit Judges.

The panel has voted to deny Pom Wonderful LLC's Petition for Rehearing and for Rehearing En Banc. The panel has voted unanimously to deny the petition for rehearing. Judges O'Scannlain and N.R. Smith have voted to deny the petition for rehearing en banc, and Judge Nelson has so recommended. The full court has been advised of the petition for rehearing en banc, and

no active judge has requested a vote on whether to rehear the matter en banc. Fed. R. App. P. 35.

Pom Wonderful LLC's Petition for Rehearing and for Rehearing En Banc is DENIED.

APPENDIX C

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

POM WONDERFUL LLC, a Delaware limited liability company,
Plaintiff,

v.

THE COCA COLA COMPANY, a Delaware corporation; and DOES 1-10, inclusive
Defendants.

Case No. CV-08-06237 SJO (FMOx)
May 24, 2010

FINAL JUDGMENT

Hon. S. James Otero

WHEREAS:

The Court has reviewed the Amended [Proposed] Pretrial Conference Order ("PTCO") filed by Plaintiff Pom Wonderful LLC ("Plaintiff") and Defendant The Coca-Cola Company ("Defendant");

The Court has issued its Order Granting In Part, Denying In Part Defendant's Motion For Summary Judgment Pursuant To Fed. R. Civ. P. 56; Denying Plaintiff's Motion For Partial Summary Adjudication Re: Defendant's Affirmative Defenses Of Safe Harbor And Compliance with Laws, entered on May 5, 2010 [Docket No. 360] (the "MSJ Order");

The MSJ Order dismissed Plaintiff's state law claims. The MSJ Order also "precluded [Plaintiff] from pursuing its Lanham Act claim against the naming and labeling on the Juice's bottle," MSJ Order at 33, and "precluded [Plaintiff] from pursuing its Lanham Act claim against the Fruit Vignette." *Id.* at 36. The MSJ Order did not preclude Plaintiff from pursuing its Lanham Act claim in other respects;

Plaintiff stipulates that, in light of the Court's MSJ Order, it cannot now carry its burden with respect to its Lanham Act claim and that, accordingly, the Court should dismiss with prejudice the remaining portion of Plaintiff's Lanham Act claim and enter Final Judgment for Defendant in this action with respect to all claims;

Plaintiff has expressly reserved its right to appeal this Final Judgment and the Court's prior orders in this matter including, but not limited to, the MSJ Order;

IT IS ORDERED AND ADJUDGED THAT final judgment is hereby entered in favor of Defendant The Coca-Cola Company.

Dated: May 24, 2010

By: /s/ S. James Otero
Hon. S. James Otero
United States District Judge

Respectfully submitted by:

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By: /s/ Daniel S. Silverman
Daniel S. Silverman
Attorneys for Plaintiff
POM WONDERFUL LLC

PATTERSON BELKNAP WEBB & TYLER LLP

By: /s/ Steven A. Zalesin
Steven A. Zalesin
Attorneys for Defendant
THE COCA-COLA COMPANY

APPENDIX D

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

POM WONDERFUL LLC,
Plaintiff,

v.

THE COCA COLA COMPANY,
Defendant.

No. CV 08-06237 SJO (FMOx)
May 5, 2010

ORDER GRANTING IN PART, DENYING IN PART DEFENDANT'S MOTION FOR SUMMARY JUDGMENT PURSUANT TO FED. R. CIV. P. 56; DENYING PLAINTIFF'S MOTION FOR PARTIAL SUMMARY ADJUDICATION RE: DEFENDANT'S AFFIRMATIVE DEFENSES OF SAFE HARBOR AND COMPLIANCE WITH LAWS [Docket Nos. 149, 150]

S. JAMES OTERO, District Judge.

This matter is before the Court on Defendant The Coca Cola Company's ("Coca Cola" or "Defendant") Motion for Summary Judgment Pursuant to Fed. R. Civ. P. 56, filed December 28, 2009, and Plaintiff Pom Wonderful LLC's ("Pom" or "Plaintiff") Motion for Partial Summary Adjudication Re: Defendant's Affirmative Defenses of Safe Harbor and Compliance with Laws, also filed December 28, 2009. The parties filed Oppositions and Replies to the respective Motions. The Court found this matter suitable for disposition without oral argument and vacated the hearings set for January

25, 2010. *See* Fed. R. Civ. P. 78(b). For the following reasons, Coca Cola's Motion is **GRANTED IN PART** and **DENIED IN PART**, and Pom's Motion is **DENIED**.

I. *BACKGROUND*

Pom produces, markets, and sells POM WONDERFUL® brand bottled pomegranate juice and various pomegranate juice blends, including a pomegranate blueberry juice blend. (First Am. Compl. ("FAC") ¶ 11; Pl.'s Statement of Genuine Issues of Fact and Proposed Conclusions of Law in Opp'n to Def.'s Mot. for Summ. J. ("Pl.'s SOF Opp'n") ¶ 1.) Coca Cola, under the brand Minute Maid, is one of Pom's primary competitors in the bottled pomegranate juice market. (FAC ¶ 17; Pl.'s SOF Opp'n ¶ 2.) In September 2007, Coca Cola announced a new product in its "Minute Maid Enhanced Juices" line, entitled "Minute Maid® Enhanced Pomegranate Blueberry Flavored 100% Juice Blend." (FAC ¶ 18; Pl.'s SOF Opp'n ¶ 3.) The formal name of "Minute Maid® Enhanced Pomegranate Blueberry Flavored 100% Juice Blend" is "Pomegranate Blueberry Flavored Blend Of 5 Juices" ("the Juice"). (Def.'s Mot. for Summ. J. Pursuant to Fed. R. Civ. P. 56 ("Def.'s Mot.") 3; Pl.'s SOF Opp'n ¶ 3; Decl. of Charles Torrey in Supp. of Def.'s Mot. for Summ. J. ("Torrey Decl.") ¶ 3.) Specifically, in ranking the ingredients of the Juice by volume, apple ranks first, grape ranks second, pomegranate ranks third, blueberry ranks fourth, and raspberry ranks fifth. (FAC ¶ 22.)

A. *The Juice's Bottle*

"The Juice has used the same bottle and label since it was first introduced." (Pl.'s SOF Opp'n ¶ 8.) A "prominent banner or 'flag' (the "Banner") on the Juice label states 'Omega-3/D HA HELP NOURISH YOUR

BRAIN 5 Nutrients To Support Brain & Body.' " (Pl.'s SOF Opp'n ¶ 9.) Pom acknowledges that the Banner is prominent, but contends that "the text 'Omega-3/DHA' and '5 Nutrients To Support Brain & Body' is not prominently displayed." (Torrey Decl. Ex. 1, p. 9.) Above the Banner reads "100% Fruit Juice Blend," and below the Banner appears a fruit vignette (the "Fruit Vignette") that "depicts each of the five fruit ingredients in the Juice." (Torrey Decl. Ex. 1, p. 9; Pl.'s SOF Opp'n ¶¶ 10, 11.) Specifically, the Fruit Vignette includes images of a half-cut pomegranate, a half-cut apple, and several blueberries, grapes, and raspberries. (Torrey Decl. Ex. 1, p. 9.) Below the Fruit Vignette reads "Pomegranate Blueberry," and below that, "Flavored Blend Of 5 Juices." (Torrey Decl. Ex. 1, p. 9.) "The back of the Juice bottle reads 'Minute Maid Enhanced Pomegranate Blueberry Is Made With A Blend Of Apple, Grape, Pomegranate, Blueberry, And Raspberry Juices From Concentrate And Other Ingredients.' " (Torrey Decl. Ex. 1, p. 9.) It is undisputed that "[t]he back of the bottle does not include other references to pomegranates or blueberries." (Pl.'s SOF Opp'n ¶ 16.)

B. *The Juice's Advertisements*

Coca Cola advertises the Juice "through television and print ad[vertisements], coupons, in-store promotions, and on the Minute Maid website." (Pl.'s SOF Opp'n ¶ 17.) Coca Cola maintains that its "brain-nourishment" claims, which form the centerpiece of the Juice's advertising and marketing campaign, "are based upon the unique combination of added nutrients, including not only Omega-3/DHA, but also choline, vitamin B-12, vitamin E, and vitamin C, all of which have been

shown to contribute to brain development."[1] (Def.'s Mot. 3.) Coca Cola, therefore, contends that its "help nourish your brain" claim is fully substantiated, and that in fact, the National Advertising Division of the Council of Better Business Bureaus ("NAD") concluded that "[Coca Cola] ha[s] a reasonable basis for its claim that [the Juice] can 'help nourish your brain.' " (Def.'s Mot. 3; Decl. of Steven A. Zalesin in Supp. of Def.'s Mot. for Summ. J. ("Zalesin Decl.") Ex. 2.) "Pom does not contest the scientific accuracy of this claim." (Def.'s Mot. 3.) As such, Coca Cola argues that its advertising and marketing, separate and apart from the naming and labeling of the Juice, focus on the Juice's added nutrients and "brain nourishment," not on the Juice's pomegranate or blueberry content. (Def.'s Mot. 3.) Coca Cola further notes that its "[o]ther ads similarly emphasize that the Juice tastes great." (Def.'s Mot. 3.)

1. *Coupons*

Coca Cola contends that its "coupons have included pictures of the Juice bottle, but have focused on savings, rather than the fruit ingredients in the product," and that "in-store promotional materials describe

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[1] The Court notes the Food and Drug Administration's ("FDA") February 23, 2010 Warning Letter to Pom. *See* Letter from Roberta C. Wagner, to Matt Tauper (Feb. 23, 2010) (on file with the Court) ("Your POM Wonderful 100% Pomegranate Juice and POMx products are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners ... Thus, your products are misbranded under Section 502(f)(1) of the Act, in that the labeling for these drugs fails to bear adequate directions for use [21 U.S.C. § 352(f)(1)] ... Your [product] is also a misbranded food within the meaning of Section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)] because the product bears a nutrient content claim that does not meet the requirements to make the claim.").

the Juice as a 'Pomegranate Blueberry Flavored 100% Juice Blend' or 'Pomegranate Blueberry Flavored Blend Of 5 Juices,' and [have] pictured the bottle sometimes next to its fruit ingredients—but have made no other references to pomegranates or blueberries." (Pl.'s SOF Opp'n ¶¶ 18, 20; Torrey Decl. Exs. 2, 3.) Pom, on the other hand, alleges that Coca Cola's "coupons prominently feature, in large text, the name 'POMEGRANATE BLUEBERRY,' " and that "[t]he promotional materials further display images of pomegranates only—and no other fruit—which are heaped about the bottle." (Pl.'s SOF Opp'n ¶¶ 18, 20; Pl.'s Statement of Additional Material Facts ("Pl.'s Addt'l SOF") ¶¶ 39-40; Torrey Decl. Exs. 2, 3.)

2. *Print Advertisements*

Coca Cola's print advertising has included campaigns entitled 'Love it or it's free!,' 'Helps nourish your brain and your sense of taste,' 'help nourish your brain,' 'OOPS Someone forgot to boost,' and 'You².' (Torrey Decl. Ex. 4; Pl.'s SOF Opp'n ¶¶ 22-23.) Coca Cola argues that these "print advertisements all featur[ed] pictures of the [Juice] bottle with few other references to pomegranates." (Pl.'s SOF Opp'n ¶ 22.) Coca Cola states that "[the Juice's] print ads [have] focused on the nutritional benefits of the Omega-3D/DHA fortification and the product's great taste rather than the Juice's pomegranate juice content." (Pl.'s SOF Opp'n ¶ 24.)

Pom disputes whether the focus of Coca Cola's print advertisements is solely on the nutritional benefits of the Omega-3/DHA fortification, and the Juice's good taste, and not on the Juice's pomegranate juice content. (Pl.'s SOF Opp'n ¶¶ 22, 24; Torrey Decl. Ex. 4.) Pom argues that Coca Cola's print advertisements

prominently display the words "Blueberry Pomegranate." (Pl.'s SOF Opp'n ¶¶ 24, 25, 26.) Pom cites Coca Cola's print advertisements, which include "Minute Maid Pomegranate Blueberry flavored juice blend packs goodness for your brain and body in every sip" as illustrative of Coca Cola's emphasis on the Juice's pomegranate blueberry content. (Pl.'s SOF Opp'n ¶ 24.) Furthermore, Pom cites one print advertisement that depicts only the top half of the Juice's bottle, thereby excluding "Pomegranate Blueberry Flavored Blend Of 5 Juices." (Torrey Decl. Ex. 4, p. 36.)

3. *Television Advertisements*

Coca Cola maintains that the television advertisements used to promote the Juice have "flashed images of the five fruit ingredients, but have made no other references to pomegranates or blueberries." (Pl.'s SOF Opp'n ¶ 29.) "For example, [Coca Cola cites] the 'We Meet Again' commercial, [that] focused on a man who mistook his daughter's art teacher for an ex-girlfriend before drinking the Juice, but correctly identified her afterwards." (Pl.'s SOF Opp'n ¶ 30.) Coca Cola argues:

> The commercial showed the man drinking from the bottle, displayed the bottle and its 'Help Nourish Your Brain' flag on its own, and flashed the Juice's five fruit ingredients ... An announcer described the Juice as 'Minute Maid Enhanced with a five-nutrient boost,' but made no mention of pomegranates or blueberries.

(Pl.'s SOF Opp'n ¶ 31.)

Pom, on the other hand, contends that Coca Cola's television advertising identifies the Juice as a "pomegranate and blueberry juice blend," first, and makes no

explicit reference to the Juice's flavor. (Pl.'s SOF Opp'n ¶ 29; Pl.'s Addt'l SOF ¶¶ 41, 42.) Pom further alleges that the paper copy that Coca Cola submitted as evidence of the "Help Nourish Your Brain" commercial "does not depict the Juice's five fruit ingredients." (Pl.'s SOF Opp'n ¶ 31.)

4. *The Minute Maid Website*

Finally, Coca Cola maintains that its "Minute Maid website [the "Enhanced Juices Website"] contains information about the Juice."[2] (Torrey Decl. Ex. 6; Pl.'s SOF Opp'n ¶ 33.) Coca Cola states that "[r]eferences to the Juice are on [the Enhanced Juices Website], and [also] in a section of the website dedicated to the Juice [the Juice Webpage]" (collectively, the "Minute Maid Webpages"). (Pl.'s SOF Opp'n ¶ 34.) Pom disputes whether the Enhanced Juices Website includes "sections," as Coca Cola contends, but otherwise agrees that the Minute Maid Webpages focus on the Juice's "product and nutrition information, storage tips, the benefits of the Juice's added ingredients, and games re-

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[2] The Court notes that the parties refer to www.minutemaid.com in their pleadings, but when the Court attempted to access said website, it was directed to www.minutemaid.com/index.jsp. (Pl.'s SOF Opp'n ¶ 33.) Furthermore, because the parties identify said website as including references to the Juice, as well as depicting the full Minute Maid® Enhanced Juice and Juice Drink line, it is assumed that the parties intend to refer to www.minutemaid.com/EnhancedJuices.jsp, which includes those features. Accordingly, the Court will refer to www.minutemaid.com/EnhancedJuices.jsp as the Enhanced Juices Website because it most closely parallels that which the parties refer to in their pleadings. To that end, the Enhanced Juices Website provides access to the "Minute Maid® Enhanced Pomegranate Blueberry" page, www.minutemaid.com/PomegranateBlueberry.jsp, which includes even more information about the Juice, and will be referred to as the "Juice Webpage."

lated to the Juice."[3] (Pl.'s SOF Opp'n ¶ 35.) Regardless of whether the relevant webpages form the same website, there are two distinct pages, one that relates to the Minute Maid® Enhanced Juices & Juice Drinks, generally, and which will be referred to as the Enhanced Juices Website, and one that relates to the Juice, specifically, and which will be referred to as the Juice Webpage. (Torrey Decl. 6.)

Coca Cola contends that "[h]eadings on [Minute Maid Webpages] refer to the Juice as 'Minute Maid® Enhanced Pomegranate Blueberry Flavored 100% Juice Blend,' " but which Pom contests.[4] (Pl.'s SOF Opp'n ¶ 36.) Instead, Pom argues that the "Flavored 100% Juice Blend" is in "a different text and font color, ... [and] far smaller than the header [Minute Maid® Enhanced Pomegranate Blueberry]." (Pl.'s SOF Opp'n ¶ 36; Torrey Decl. Ex. 6, p. 47.) Because "Flavored 100% Juice Blend" is also located on a lower line, Pom argues that the header consists of only "Minute Maid® Enhanced Pomegranate Blueberry." (Pl.'s SOF Opp'n ¶ 36; Torrey Decl. Ex. 6, p. 47.)

The parties disagree over other features of the Juice Webpage, too. Coca Cola asserts that the Juice Webpage sufficiently emphasizes " 'Minute Maid® Enhanced Pomegranate Blueberry Flavored 100% Juice

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[3] The Enhanced Juices Website includes a row of different words, each of which provides information relating to a different topic. The row includes the following "topics:" (1) Products; (2) Healthy Living; (3) Recipes; (4) About Us; (5) Promotions; (6) News; and (7) Downloads.

[4] Here, it is clear that Coca Cola intends to cite to what the Court refers to as the Juice Webpage, since the Enhanced Juices Website does not include any heading that reads "Minute Maid® Enhanced Pomegranate Blueberry Flavored 100% Juice Blend."

Blend,' " and places "no emphasis on pomegranates or pomegranate juice, let alone on the specific health benefits (e.g., reduced risk of cancer) that Pom claims [Coca Cola] provide[s]." (Pl.'s SOF Opp'n ¶ 40; Torrey Decl. Ex. 6, p. 47.) The Juice Webpage contains the following language:

> Minute Maid® Enhanced Pomegranate Blueberry is a great tasting flavored 100% juice blend with 50mg of Omega-3/DHA per 8 fl. oz. serving and four other nutrients to help nourish your brain and body. Find it in the chilled juice section of your local store.

(Torrey Decl. Ex. 6, p. 47.) Below this language is an icon entitled "get product information," that links to another page (the "Get Information Page") that includes additional information about the Juice:

> Minute Maid Enhanced Pomegranate Blueberry is a great tasting flavored 100% juice blend with 50mg of Omega-3/DHA per 8 fl. oz. serving and four other nutrients to help nourish your brain and body. By combining natural fruit juices and targeted fortification, this new Minute Maid Enhanced Juice delivers enhanced nutrition, and is a perfect addition to a healthy diet.

(Torrey Decl. Ex. 6, p. 48.) Still more, an icon entitled "Nutrition Information" on the Get Information Page, links to another page that contains the Juice's nutritional information (the "Nutritional Information Page"). (Torrey Decl. Ex. 6, p. 50.) The Nutritional Information Page states that the Juice contains apple, grape, and pomegranate juices from concentrate, blueberry juice from concentrate, natural flavors, and rasp-

berry juice from concentrate. (Torrey Decl. Ex. 6, p. 50.)

Consequently, Pom contends that the Minute Maid Webpages emphasize the Juice's pomegranate and blueberry juice content. (Pl.'s SOF Opp'n ¶¶ 36-40.) Pom notes that Minute Maid's Brand Director, Ashley Ann Schmidt, confirmed that the Minute Maid Webpages are intended to advertise and market the Juice.[5] (Pl.'s Addt"l SOF ¶ 5.)

C. *Pom's Allegations Against Coca Cola*

"[T]he main ingredients in [the Juice] are neither pomegranate, nor blueberry juice, but rather, apple and grape juice." (FAC ¶ 19; *supra* Part I.) Specifically, the Juice "contains only 0.3% pomegranate juice and 0.2% blueberry juice." (Pl.'s Addt'l SOF ¶ 1; Silverman Decl. Ex. F.) By contrast, "[a]pple and grape juices make up more than 99.4% of the Juice's contents, with the fifth type of juice, raspberry juice, making up just 0.1%." (Pl.'s Addt'l SOF ¶ 1; Silverman Decl. Ex. F.) Therefore, Pom contends that Coca Cola labels the Juice as a "Pomegranate Blueberry" juice, and advertises and markets it, through its packaging, commercials, Minute Maid Webpages,[6] and other forms of ad-

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[5] The Court notes that Ms. Schmidt used the language "the Website," which is terminology that the Court has since abandoned because it is an overly broad definition of the Minute Maid Webpages. It is, however, irrelevant whether Ms. Schmidt intended to refer to the Enhanced Juices Website or the Juice Webpage. What is important is whether Minute Maid intends to use the Minute Maid Webpages as a form of communicating to consumers.

[6] The Court again notes that the parties' references to "the Minute Maid website" encompasses both the Enhanced Juices Website and the Juice Webpage.

vertising, "based on the representation that the Juice's primary ingredients ... are pomegranate and blueberry juice, when, in fact, the primary ingredients are actually apple and grape juice." (FAC ¶¶ 8, 20.) Accordingly, Pom alleges that consumers of the Juice "are likely to be misled and deceived by [its] ... labeling, marketing and advertising," which damages not only the consuming public, but also Pom, as Coca Cola's competitor. (FAC ¶¶ 23-26.)

1. *Consumer Complaints*

Pom contends that Coca Cola has received a record number of complaints regarding the Juice. (Pl.'s Addt'l SOF ¶¶ 16-23; *see generally* Nancy Tyndal Dep. 11-15, 43-49, 252, Dec. 10, 2009.) Nancy Tyndal ("Tyndal"), a fourteen-year employee of Coca Cola, and who has "field[ed] consumer complaints about many products, ... asserts that there have been no Minute Maid products about which consumers have complained more." (Nancy Tyndal Dep. 252:6-18, Dec. 10, 2009.) Indeed, Pom provides a list of consumer complaints provided to it by Coca Cola, and which Pom contends suggests that consumers have been misled into believing that the Juice was something for which it is not. (Pl.'s Addt'l SOF ¶¶ 19-23.) For example, one consumer complaint reads:

> Today I made the mistake of buying [the] Minute Maid product that you call 'Pomegranate Blueberry[.]' What a crock. It's nothing but fancy apple grape juice. You people are scumbags for mislabeling your products. I'll never buy this product again. I'll never buy Minute Maid products again. And I'll tell all of my

> friends about this fraud. Thanks for wasting my time and money ....[7]

(Pl.'s Addt'l SOF ¶ 19; Pl.'s Opp'n 3-4.) The Court notes that Pom has referenced several other similar complaints, but concludes that it unnecessary to reference them all. (Pl.'s Opp'n 4.)

2. *The Field Survey*

"Pom commissioned Dr. E. Deborah Jay ("Dr. Jay") to conduct a survey (the "Field Survey") that assesse[d] consumer confusion in connection with [Coca Cola's] advertising of the Juice."[8] (Pl.'s SOF Opp'n ¶

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[7] The Court notes Coca Cola's opposition to Pom's inclusion of "selected consumer complaints." (*See generally* Def.'s Objections to Evidence Presented in Conjunction with Pl.'s Opp'n to Summ. J. ("Def.'s Objections to Evidence")) Pom, however, alleges that the complaints it cites and relies upon, were produced by Coca Cola. (Silverman Decl. ¶¶ 15-19.) In any event, even if the Court declines to address the consumer complaints to which Coca Cola objects, Nancy Tyndal, a Coca Cola employee, states that in her experience, the Juice has received more complaints than any other Minute Maid product. (Silverman Decl. Ex. L.)

[8] Dr. Jay is the President and CEO of Field Research Corporation, which is, according to Pom, one of the oldest and most respected marketing and public opinion research firms in the United States. (Pl.'s Addt'l SOF ¶ 24.) The Field Survey was conducted with 538 face-to-face double-blind interviews of adults age 18 and older who believed they would purchase a pomegranate juice blend and a blueberry juice blend in the next three months. (Pl.'s Addt'l SOF ¶ 25.) "The Field Survey interviewed a 'test' group of respondents who were shown the Juice's actual bottle label, along with a 'control' group of respondents who were shown a slightly modified bottle with the words 'Pomegranate Blueberry' removed from the front and back label." (Pl.'s Addt'l SOF ¶ 26.) According to Pom, "36% of the test group in the Field Survey indicated that they believed the Juice mainly contains pomegranate and blueberry juice, and not other types of fruit juice." (Pl.'s Addt'l SOF ¶ 27.) "32% of the test group in the Field Survey indicated that they be-

43; Pl.'s Addt'l SOF ¶¶ 24-33.) Dr. Jay concluded that "a substantial proportion of potential purchasers of pomegranate and blueberry juice blends are likely to mistakenly believe that [the Juice] mainly contains pomegranate and blueberry juice (and not other types of fruit juice) due to the packaging (the words 'pomegranate blueberry' on the front of the bottle and in the product name on the back of the bottle)." (Pl.'s SOF Opp'n ¶ 47.) Pom notes that "Dr. Jay did not purport to conclude that this was the only consumer confusion which exists regarding the Juice, or that such confusion is limited to the bottle, as opposed to other means of false advertising." (Pl.'s SOF Opp'n ¶ 47.) Pom further contends that "[t]he 35% differential which the Field Survey found between the test and control groups' respective belief that the Juice only contains pomegranate and blueberry juice far exceeds the percentage that district courts typically find acceptable for a consumer survey in support of a Lanham Act claim." (Pl.'s Opp'n 5.) Therefore, Pom argues that the Field Survey demonstrates the misleading effect that the Minute Maid Webpages have on consumers, so that consumers are likely "to believe that the Juice *mainly* contains pomegranate and blueberry juice (and not other types of fruit juice)." (Pl.'s Addt'l SOF ¶¶ 32-33.) Accordingly, Pom claims that "[t]he Field Survey evidences the misleading effect of [Coca Cola's] decision to identify

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lieved the Juice mainly contains pomegranate and blueberry juice, and not other types of fruit juice, *because of the words* 'pomegranate blueberry' on the label." (Pl.'s Addt'l SOF ¶ 28) (emphasis added.) Finally, Pom contends that "1% of the control group in the Field Survey indicated that they believed the Juice mainly contains pomegranate and blueberry juice, and *not other types of fruit juice*." (Pl.'s Addt'l SOF ¶ 29) (emphasis added.)

the Juice by the name 'Pomegranate Blueberry.' " (Pl.'s Addt'l SOF ¶ 31.)

Principally, Coca Cola contests the efficacy of the Field Survey. (Pl.'s SOF Opp'n ¶¶ 43-47.) First, Coca Cola argues that "[t]he only stimulus shown to the survey participants was the bottle and the label of the Juice," and so, the Field Survey did "not attempt to evaluate the messages conveyed by Minute Maid's website or any of [Coca Cola's] other advertising." (Pl.'s SOF Opp'n ¶ 45; Def.'s Mot. 3-4.) Coca Cola notes that "[t]he [Field] [S]urvey found that the main message the [Juice's] bottle communicated to most consumers was that 'the product is healthy, nutritious, nourishes the brain, is good for you, has Omega-3/DHA or has other vitamins and nutrients.' " (Pl.'s SOF Opp'n ¶ 46.) Finally, Coca Cola alleges that "Dr. Jay concluded that any consumer confusion about the [Juice] was due to packaging (the words 'pomegranate blueberry' on the front of the bottle and in the product name on the back of the bottle)," and not due to the Juice's advertising or marketing. (Pl.'s SOF Opp'n ¶ 47.)

3. *Coca Cola's Alleged Knowledge That the Juice Is Misleading*

Finally, Pom argues that Coca Cola knew that the Juice was misleading, but willingly assumed the advertising risk that any misconception necessarily created. (Pl.'s Opp'n to Def.'s Mot. for Summ. J. ("Pl.'s Opp'n") 3.) Pom cites a correspondence between Coca Cola employees sent prior to the Juice's launch, and which allegedly illustrates Coca Cola's intent to launch a misleading product:[9]

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[9] The correspondence at issue here was sent by A. Lucy Reid ("Reid"), Coca Cola's Director of Scientific and Regulatory Affairs,

> As discussed here is a copy of the front label for the new MM Enhanced Juice Pomegrante [sic] Blueberry product. The product has a blend of apple, grape, pomegranate, blueberry & raspberry juices from conc. We are in compliance with the FDA regs related to the naming of juice containing products. There is a risk from a misleading standpoint as the product has less than 0.5% of pomegranate and blueberry juices. Mike St. John is aware of this issue & is willing to assume the risk.

(Silverman Decl. Ex. H; Pl.'s Opp'n 3; Pl.'s Addt'l SOF ¶¶ 6-7.) According to Pom, "[t]his e-mail constitutes damning evidence of [Coca Cola's] willful consumer deception." (Pl.'s Opp'n 3.)

D. *Procedural History*

Based on the above-mentioned facts, Pom brought suit against Coca Cola on September 22, 2008, alleging causes of action for: (1) false advertising under the Lanham Act, 15 U.S.C. § 1125(a); (2) false advertising under California Business and Professions Code § 17500; and (3) statutory unfair competition under California Business and Professions Code § 17200. (*See* FAC ¶¶ 28-50.) On February 10, 2009, the Court denied in part, and granted in part, Coca Cola's Motion to Dismiss (the "First Motion to Dismiss"). (*See* Order of Feb. 10, 2009.) Specifically, the Court granted in part Coca Cola's First Motion to Dismiss Pom's Lanham Act claim "only to the extent it challenges the Juice's formal name and labeling in areas for which the FDA has

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to Reid's boss, Mike St. John ("St. John"), President and General Manager of Minute Maid. (Pl.'s Opp'n 3; Pl.'s Addt'l SOF ¶¶ 6-7; Silverman Decl. Exs. G, H.)

promulgated regulations implementing the [Federal Food, Drug, and Cosmetic Act]."[10] (*See* Order of Feb. 10, 2009.) Regarding Pom's state law claims, the Court granted in part Coca Cola's First Motion to Dismiss "to the extent [the state law claims] seek to impose any obligations that are 'not identical to' the sections of the FFDCA ...." (See Order of Feb. 10, 2009.) The Court concluded:

> [t]o the extent the safe harbor doctrine applied in this case, it would only bar Pom's claim for statutory unfair competition under California Business and Professions Code § 17200 with respect to "business practices specifically permitted" or conduct "clearly permit[ted]" by the FFDCA .... [However,] [b]ecause Coca Cola merely contends that the safe harbor doctrine applies to the 'FDA's Juice naming regulations' and the Court has already held that Pom's state law claims are expressly preempted to the extent they seek to impose obligations differing from those contained in the FFDCA and

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[10] The Federal Food, Drug, and Cosmetic Act ("FFDCA"), also referred to as the Federal Drug and Cosmetic Act ("FDCA"), gives the FDA authority to promulgate regulations that govern the branding of food, in order to "promote honesty and fair dealing in the interest of consumers." 21 U.S.C. §§ 301, 341. "Under 21 U.S.C. § 337(a), the FDCA provides that 'all such proceedings for the enforcement, or to restrain violations of [the Act] shall be by and in the name of the United States.' Courts have generally interpreted this to mean that no private right of action exists to redress alleged violations of the FDCA." *Summit Technology, Inc. v. High-Line Medical Instruments Co., Inc.*, 922 F. Supp. 299, 305 (C.D. Cal. 1996) (internal citations omitted); *Ginochio v. Surgikos, Inc.*, 864 F. Supp. 948, 956 (N.D. Cal. 1994) (citing various courts that have held that "there is no private cause of action for violations of the [FDCA]").

> its accompanying FDA regulations regarding the Juice's "common or usual name," the safe harbor would not extend beyond the portion of the claims that the Court has already found to be expressly preempted by the FFDCA.

(*See* Order of Feb. 10, 2009.)

Following the filing of Pom's FAC on July 27, 2009, Coca Cola filed a Motion to Dismiss First Amended Complaint Pursuant to Fed. R. Civ. P. 12(b)(6) (the "Second Motion to Dismiss"). (*See generally* FAC.) The Court "reasserted its previous position" and denied Coca Cola's Second Motion to Dismiss. (*See* Order of Sept. 15, 2009, 2009 WL 6254619.) The Court concluded that "FDA juice-naming and labeling regulations do not bar Pom from alleging that Coca Cola has advertised or marketed the Juice in a misleading manner on its website and in other advertising avenues ... at this motion to dismiss stage it is unnecessary to demarcate and identify which (if any) of the allegations in the FAC are within the FDA's sole purview, and which allegations are encompassed by the Lanham Act." (*See* Order of Sept. 15, 2009.) Moreover, regarding Pom's state law claims, the Court permitted Pom to establish that Coca Cola's profits can be " 'traced to ill-gotten funds,' which would [therefore,] be a 'vested' interest, and entitle Pom to restitution." (*See* Order of Sept. 15, 2009.) However, without more facts before it, the Court declined to preclude Pom from pursuing its state law claims at the motion to dismiss stage.

Coca Cola now moves for summary judgment, arguing that "Pom can point to no evidence that [Coca Cola's] marketing or advertising for the Juice—as distinguished from [the Juice's] name and label—is false or misleading." (Def.'s Mot. 2) Pom, too, moves for partial

summary adjudication, on the grounds that applicable law does not provide Coca Cola with the "safe harbor" or "compliance with laws" affirmative defenses to Pom's claims, and which are asserted pursuant to the Lanham Act § 43(a) ("the Lanham Act") and Cal. Bus. & Prof. Code §§ 17200 and 17500. (*See* Pl.'s Notice of Mot. and Mot. for Partial Summ. J. Re: Def.'s Affirmative Defenses of Safe Harbor and Compliance with Laws; Mem. of P. & A. ("Pl.'s Mot.") 2.)

II. *DISCUSSION*

A. *Standard for Summary Judgment*

Summary judgment is proper only if "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact." Fed. R. Civ. P. 56(c). A "material" fact is one that could affect the outcome of the case under the governing substantive law, and an issue of material fact is "genuine" if "the evidence is such that a reasonable jury could return a verdict for the non[-]moving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986); *see Atlanta Attachment Co. v. Leggett & Platt, Inc.*, 516 F.3d 1361, 1365 (Fed. Cir. 2008) (internal citation omitted).

In determining whether a genuine issue of material fact exists, the court must not make credibility determinations or weigh conflicting evidence. *Anderson*, 477 U.S. at 255, 106 S. Ct. 2505. Rather, the court must view the evidence in the light most favorable to the non-moving party, drawing all "justifiable inferences" in its favor. *Id.* (internal citation omitted); *see Atlanta Attachment Co.*, 516 F.3d at 1365 (internal citation omitted); *Group One, Ltd. v. Hallmark Cards, Inc.*, 254

F.3d 1041, 1045 (Fed. Cir. 2001) (internal citations omitted).

B. *The Lanham Act*

"Under the Lanham Act, any person that uses a 'false description or representation' that is 'in connection with any goods' is liable to another private individual 'who believes he is or is likely to be damaged by the use of any such false description or representation.'" *Pom Wonderful LLC v. Ocean Spray Cranberries, Inc.* ("*Ocean Spray*"), 642 F. Supp. 2d 1112, 1117 (C.D. Cal. 2009)[11]; *see Jack Russell Terrier Network of Northern California v. American Kennel Club. Inc.*, 407 F.3d 1027, 1036 (9th Cir. 2005); 15 U.S.C. § 1125(a).[12] Indeed,

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[11] "After filing the present action, Pom filed three other actions in the Central District of California, alleging that Tropicana Products ("Tropicana"), Ocean Spray Cranberries, Inc. ("Ocean Spray"), and Welch Foods, Inc. ("Welch's") misrepresent the amount of pomegranate juice ... contained in their blended juice products." (Pl.'s Opp'n 6.) The Court notes that although the three sister cases are similar to the present case, they are also factually distinguishable. For example, although Pom cites *Ocean Spray*, the Ocean Spray label arguably includes a greater number of references to pomegranate juice, including "If you're a cranberry or pomegranate lover this juice should make you 100% happy!" and "We've combined two anti-oxidant powerhouses, the cranberry and pomegranate, along with other tasty juices." As such, in Ocean Spray, Judge Dean D. Pregerson concluded that he did not find that "the essential claim advanced by [the] [p]laintiff—that [the] [d]efendant's label misrepresents the primary ingredients of the Beverage—relies on a determination by the FDA or an interpretation of its regulations." *Ocean Spray*, 642 F. Supp. 2d at 1119.

[12] Section 43(a) of the Lanham Act as amended, states: (1) Any person who, on or in connection with any goods or services, or any container for goods, used in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or

the Lanham Act is designed to protect commercial interests from a competitor's false advertising and to protect the business community from having its reputation and good will diverted. *See Phoenix v. McDonald's Corp.*, 489 F.3d 1156, 1168 (11th Cir. 2007); *see also Schering-Plough Healthcare Products, Inc. v. Schwarz Pharma, Inc.*, 586 F.3d 500, 512 (7th Cir. 2009) ("The purpose of the false-advertising provisions of the Lanham Act is to protect sellers from having their customers lured away from them by deceptive ads or labels, or other promotional materials."). To establish a false advertising claim under the Lanham Act, a plaintiff must demonstrate that the challenged description or representation is false. *Gonzalez v. Allstate Ins. Co.*, 2005 WL 5891935, *5 (C.D. Cal. Aug. 2, 2005). "Falsity may be established by proving that (1) the advertising is literally false as a factual matter, or (2) although the advertisement is literally true, it is likely to deceive or confuse consumers."[13] *Lipton v. Nature Co.*, 71 F.3d

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misleading representation of fact, which—(A) is likely to cause confusion, or to cause mistake or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his goods, services, or commercial activities by another person, or (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act. 15 U.S.C. § 1125(a).

[13] Some courts frame the requirements for establishing a false advertising claim under § 43(a) of the Lanham Act differently, requiring that plaintiffs show: (1) a false statement or fact by the defendant in a commercial advertisement about its own or another's product; (2) the statement actually deceived or has the tendency to deceive a substantial segment of its audience; (3) the deception is material, in that it is likely to influence the purchasing decision; (4) the defendant caused its false statement to enter in-

464, 474 (2d Cir. 1995); *see Southland Sod Farms*, 108 F.3d 1134, 1139 (9th Cir. 1997) ("[t]o demonstrate falsity within the meaning of the Lanham Act, a plaintiff must show that an advertisement is literally false, ... or that the statement was literally true but likely to mislead or confuse consumers.");[14] *see Mutual Pharm. Co. v. Watson Pharm., Inc.* ("*Mut. Pharm. Co. II*"), 2009 WL 3401117 (C.D. Cal. Oct. 19, 2009). "[T]he Lanham Act encompasses more than blatant falsehoods. It embraces 'innuendo, indirect intimations, and ambiguous suggestions' evidenced by the consuming public's misapprehension of the hard facts underlying an advertisement." *The Procter & Gamble Co. v. Chesebrough-Pond's Inc.*, 747 F.2d 114, 119 (2d Cir. 1984) (internal

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terstate commerce; (5) the plaintiff has been or is likely to be injured as a result of the false statement, either by direct diversion of sales from itself to defendant or by a lessening of the good will associated with its products. *Del Webb Cmty., Inc. v. Partington*, 2009 WL 3053709 (D. Nev. Sept. 18, 2009) (citing *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir. 1997)); *see CKE Rest. v. Jack In The Box, Inc.*, 494 F. Supp. 2d 1139, 1143-1148 (C.D. Cal. 2007). Either way, Pom must show that Coca Cola made false or misleading advertisements, and that Coca Cola's advertisements deceived a substantial segment of its audience. Thus, regardless of how the Court frames the test, the principal two requirements for establishing liability under § 43(a) of the Lanham Act remain the same.

[14] "To constitute commercial advertising or promotion, a statement of fact must be: (1) commercial speech; (2) by the defendant who is in commercial competition with the plaintiff; (3) for the purpose of influencing consumers to buy defendant's goods or services. While the representations need not be made in a 'classic advertising campaign,' but may consist instead of more informal types of 'promotions,' the representations (4) must be disseminated sufficiently to the relevant purchasing public to constitute 'advertising' or 'promotion' within that industry." *Mut. Pharm. Co. II*, 2009 WL 3401117 at *3 (citing *Coastal Abstract Service, Inc. v. First American Title Ins. Co.*, 173 F.3d 725, 735 (9th Cir. 1999)).

citations omitted); *see Cytosport, Inc. v. Nature's Best, Inc.* ("*Cytosport*"), 2007 WL 1345379, *1 (E.D. Cal. May 8, 2007); *see Cottrell, Ltd. v. Biotrol Int'l, Inc.* ("*Cottrell*"), 191 F.3d 1248, 1252 (10th Cir. 1999); *see also Pfizer, Inc. v. Miles, Inc.*, 868 F. Supp. 437, 442 (D. Conn. 1994) (holding that [the Lanham Act] embraces false impressions, innuendo, and ambiguous suggestions). Moreover, the Lanham Act covers only "commercial advertising or promotion." *Schwarz Pharma, Inc. v. Breckenridge Pharm., Inc.*, 388 F. Supp. 2d 967, 981 (E.D. Wisconsin 2005) (citing *Sanderson v. Culligan Intern., Co.*, 415 F.3d 620, 624 (7th Cir. 2005) and *First Health Group Corp. v. BCE Emergis Corp.*, 269 F.3d 800, 803 (7th Cir. 2001)).

Finally, because "[t]he Lanham Act and the FFDCA have overlapping jurisdiction in areas such as marketing and product labeling, though the purposes of the two statutes are different," the Court now turns to an analysis of the FFDCA and FDA. *Ocean Spray*, 642 F. Supp. 2d at 1118.

1. *The FFDCA and FDA*[15]

Compared to the Lanham Act, which is "primarily intended to protect commercial interests from unfair competition," the FFDCA, which was passed by Congress in response to "unsafe drugs and fraudulent marketing," is intended to "protect the public from unsafe or mislabeled products" by setting forth federal labeling requirements. *Wyeth v. Sun Pharm. Industries, Ltd.*, 2010 WL 746394 (E.D. Mich. Mar. 2, 2010) (citing *Wyeth v. Levine*, S. Ct. 1187, 1195 (2009))[16]; *see* 21

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[15] *See supra* note 10.

[16] The Court cites to the Supreme Court Reporter because this case has not yet been published by the U.S. Reporter.

C.F.R. §§ 101 *et seq.*; *see Schwarz Pharma, Inc.*, 388 F. Supp. 2d at 973 ("The Lanham Act provides a remedy to a plaintiff harmed by 'commercial advertising or promotion' that 'misrepresents the nature, characteristic, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities ... In contrast, the FDCA 'is not focused on the truth or falsity of the advertising claims' but on protecting the public interest in safety and efficacy of food, drugs, and cosmetics.") (internal citations omitted). Moreover, the FFDCA can only be enforced by the FDA or the Department of Justice. *Id.*; *Ocean Spray*, 642 F. Supp. 2d at 1118 (internal citations omitted).

Indeed, the FFDCA is explicit: "all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a). "When and if a claim strays too close to the exclusive enforcement domain of the FDA, it cannot stand." *Schwarz Pharma, Inc.*, 388 F. Supp. 2d at 973 (citing *Summit Tech., Inc.*, 922 F. Supp. at 306); *see Schering-Plough*, 586 F.3d at 508-09 (holding that the FDA should be given the chance to opine on the proper labeling before a Lanham Act suit is filed because it has more experience with consumers' understanding of drug labels than judges do); *see also United States v. An Article of Food ... Manischewitz*, 377 F. Supp. 746, 749 (D.C.N.Y. 1974) ("The function of the court in [sic] merely to determine whether the existing label is misleading, not to tell the [FDA] what amendments may be appropriate in order to rectify the situation.)".[17]

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[17] "The FDCA renders unlawful, inter alia, the misbranding of food and the distribution of misbranded food, [21 U.S.C. § 343; 21 U.S.C. § 331(a)-(b)], and it authorizes the FDA to enforce those

In 1990, Congress passed the Nutrition Labeling and Education Act ("NLEA"), which promulgated rules for labeling and branding foods. *See* The Nutrition Labeling and Education Act of 1990, (Public Law 101-535).[18] Specifically, the NLEA addressed the issue of when consumers may be led to believe that a named juice is present in a beverage more than is actually the case.[19] *Id.* On July 2, 1991, in response to the passage of the NLEA, the FDA published for comment, proposed rules (the "1991 proposals") pertaining to the naming and labeling of multi-juice beverages. *See* Food Labeling; Declarations of Ingredients; Common or Usual Name for Nonstandardized Foods; Diluted Juice Beverages, 56 Fed. Reg. 30452-01 (proposed July 2,

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prohibitions via enforcement actions in the United States District Courts for injunctions or criminal penalties. *Id.* at §§ 332, 333. The FDCA also delegates to the FDA certain additional tools to prevent misbranding. The FDA may, and indeed must, officially express its concerns with a warning or label before reporting a violation to a United States Attorney for criminal proceedings, to afford the regulated entity notice and an opportunity to present its views. *Id.* at § 335. In the case of 'minor violations,' the agency may issue 'a suitable written notice or warning.' *Id.* at § 336. The FDA is also delegated the authority affirmatively to regulate food labels and warnings." *See Fellner v. Tri-Union Seafoods, L.L.C.*, 539 F.3d 237, 254-55 (3d Cir. 2008).

[18] The NLEA amended the FFDCA and sought to "address concerns that the FDA had brought 'virtually no enforcement actions' against the types of claims it had previously prohibited by clarifying and strengthening 'the [FDA's] legal authority ... to establish the circumstances under which claims may be made about the nutrients in foods ...' " *Whitaker v. Thompson*, 239 F. Supp. 2d 43, 45 (D.D.C. 2003); *see* 21 C.F.R. §§ 343 *et seq.*

[19] 21 U.S.C. § 343(a) provides that a food shall be deemed misbranded if "its labeling is false or misleading in any particular way." 21 U.S.C. § 343(a).

1991) (to be codified at 21 C.F.R. §§ 101, 102).[20] The FDA expressly noted:

> [C]onsumers should be given enough accurate information to easily ascertain the nature of the juices represented to be present in a multiple-juice beverage. Many multiple-juice beverages, for example, contain only a small amount of a highly flavored, expensive juice ... Consequently, the agency is proposing to revise the current § 102.33(a) to state that if a product contains less than 100 percent juice, and uses the word "juice" in the common or usual name, then the word "juice" must be qualified by a term that indicates dilution (e.g., drink, beverage, cocktail).

Id. at 30455, 30461. The FDA further suggested:

> [I]f a product is a multiple-juice beverage or blend of single-strength juices, and declares, names, implies, or represents on the label, other than in the ingredient statement, one or more of the individual juices (represented juices), then the names of the juices so listed shall be included in the common name or usual name in descending order of predominance by volume, unless the common or usual name specifically shows that the represented flavor is used as a flavor (e.g., raspberry-flavored apple and pear juice drink) ... Thus, FDA [proposes in 21 C.F.R. § 102.33(c)] that if a diluted multiple-

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[20] Regulations under 21 C.F.R. Part 101 provide general provisions for food labeling and provide detailed regulations relating to 21 U.S.C. § 343(f). *See* 21 C.F.R. § 101.30 (regulating "any food that purports to be a beverage that contains any fruit or vegetable juices.")

> juice beverage or blend of a single-strength juice contains a represented juice and one or more that is not represented i.e., not named or implied through words or vignettes, other than in the ingredient statement, then the common or usual name for the product shall indicate that the non-represented juices are present (e.g., "Raspcranberry: raspberry and cranberry juice in a blend of two other fruit juices.")

Id. at 30462. Thus, the 1991 proposals reflected the FDA's position that a multiple-juice beverage named for a represented flavor would not necessarily be misleading. *Id.*

Thereafter, on January 6, 1993, the FDA issued final rules in response to the NLEA (the "1993 Final Rules"). *See* Food Labeling; Declarations of Ingredients; Common or Usual Name for Nonstandardized Foods; Diluted Juice Beverages, 58 Fed. Reg. 2897-01 (Jan. 6, 1993) (to be codified at 21 C.F.R. §§ 101, 102). Here, the FDA explained that if a named juice is not the predominant juice:

> The label must either state that the beverage is flavored by the named juice (e.g., "raspberry *flavored* juice drink") or declare that the content of the named juice in a 5 percent range (e.g. "raspberry juice drink 2 to 7 percent raspberry juice"). The agency believes that this approach will adequately deal with the kinds of misleading labeling discussed in the comments from consumer groups.

Id. at 2900 (emphasis added); *see* 21 C.F.R. § 102.33(b) (2009) ("If the product is a diluted multiple-juice beverage or a blend of single-strength juices and names, other than in the ingredient statement, more than one

juice, then the names of those juices must be in descending order or predominance by volume *unless the name specifically shows that the juice with the represented flavor is used as a flavor* (e.g., raspberry-flavored apple and pear juice.") (emphasis added)).

Again, the 1993 Final Rules reflected the FDA's position that multiple-juice beverages named for a represented or characteristic flavor or juice are not necessarily misleading. 58 Fed. Reg. 2897 at 2918-19 ("The basic nature of a product can be described in various ways, e.g., as a blend of five juices," and a product containing apple, grape, raspberry, and cranberry juice may include the name "Raspberry and cranberry flavored juice beverage in a blend of two other juices ... There are several ways in which a multiple-juice beverage can be appropriately labeled.").

Consequently, in accordance with the 1993 Final Rules, 21 C.F.R. § 102.33(c) states:

> If a diluted multiple-juice beverage ... contains a juice that is named or implied on the label or labeling other than the ingredient statement (represented juice) and also contains a juice other than the named or implied juice (nonrepresented juice), then the common or usual name for the product shall indicate that the represented juice is not the only juice present (e.g., "Apple blend; apple juice in a blend of two other fruit juices").

See 21 C.F.R. § 102.33(c) (2009). Similarly, 21 C.F.R. § 102.33(d) provides:

> In a diluted multiple-juice beverage or blend of single-strength juices where one or more, but not all, of the juices are named on the label oth-

> er than in the ingredient statement, and where the named juice is not the predominant juice, the common or usual name for the product shall: (1) *Indicate that the named juice is present as a flavor or flavoring* (e.g., "Raspcranberry"; raspberry and cranberry flavored juice drink); or (2) Include the amount of the named juice, declared in a 5-percent range (e.g. Raspcranberry; raspberry and cranberry juice beverage, 10- to 15-percent cranberry juice and 3- to 8-percent raspberry juice.) The 5-percent range, when used, shall be declared in the manner set forth in § 102.5(b)(2).

See 21 C.F.R. § 102.33(d) (emphasis added). In addition to that which is explained in 21 C.F.R. §§ 102 *et seq.*, the FDA adopted regulations concerning the use of the word "flavored" for all foods generally, and provides that a food may be described as "flavored" with natural flavor derived from a "characterizing" ingredient, even if little of the "characterizing" ingredient is actually present in the food. 21 C.F.R. § 101.22(i)(1)(i) explains:

> If the food is one that is commonly expected to contain a characterizing food ingredient ... and the food contains natural flavor derived from such ingredient and an amount of characterizing ingredient insufficient to independently characterize the food, or the food contains no such ingredient, the name of the characterizing flavor ... shall be immediately followed by the word '*flavored*' ....

See 21 C.F.R. § 101.22(i)(1)(i) (emphasis added).

Finally, in the 1993 Final Rules, the FDA considered whether fruit vignettes on juice labels have the potential to mislead the public, and whether such vi-

gnettes shall be FDA-regulated. *See* 58 Fed. Reg. 2897, at 2919-22. The FDA concluded:

> The agency did not [referring to previous proposals] propose a specific requirement regarding the relative amounts of the various fruits depicted in a label vignette but solicited comments on whether it should require that the vignette accurately reflect the quantity of the fruit present or the taste of the product, or whether some other requirement is appropriate ... The agency agrees that it is not always necessary that the label of a multiple-juice beverage depict each juice in a vignette. The agency believes that a vignette that pictures only some of the fruit or vegetables in the beverage *would not be misleading where the name of the food adequately and appropriately describes the contribution of the pictured juice.* For example, a 100 percent juice product consisting of apple, grape, and raspberry juices, in which the raspberry juice provides the characterizing flavor, a vignette depicting raspberries would not necessarily be misleading if the statement of identity were "raspberry juice in a blend" or "raspberry juice in a blend of two other juices, 3 to 8 percent raspberry juice." Moreover, if these three juices were in a beverage containing 50 percent total juice, a vignette picturing raspberries would not be misleading in the presence of a name like "raspberry flavored juice beverage." Accordingly, *FDA is not requiring that vignettes depict the fruit or vegetables for all juices present.* However FDA believes that a vignette that pictures the fruit or vegetable sources of all juices present

> in a product would provide useful information and thus *encourages* manufacturers to use such vignettes.

See 58 Fed. Reg. 2897 at 2918-21 (emphasis added). Thus, in the 1993 Final Rules, the FDA concluded that in the context of multi-juice beverages, manufacturers are not required to depict all the fruits or vegetables in vignettes. *Id.* at 1921-22. Instead, the FDA merely encouraged manufacturers to depict all fruits and vegetables present in the juice, as that would be instructive to consumers. Thus, in the context of vignettes on multi-juice beverages, the 1993 Final Rules reflect the FDA's position that it is an agency specifically tasked with regulating names and labels in order to prevent the misbranding of products. *Id.*

2. *Interplay Between the Lanham Act and the FFDCA*

In light of the distinction between the Lanham Act and the FFDCA, and their remedial mechanisms, a line of cases has arisen finding that Lanham Act claims are barred where private litigants ask the court to determine preemptively how the FDA will interpret and enforce its own regulations. *See Mutual Pharm. Co. v. Ivax Pharm., Inc.* ("*Mutual I*"), 459 F. Supp. 2d 925, 933 (C.D. Cal. 2006). This interplay between the Lanham Act and the FFDCA, therefore, requires "courts [to] ... tread carefully when applying the Lanham Act to advertising of goods ... that are also subject to regulation by the FDCA, lest it be used as a vehicle to accomplish indirectly something a party could not accomplish directly." *Id.*

On one hand, "[c]ourts have refused to allow a Lanham Act claim to proceed where, in order to determine the falsity or misleading nature of the representation at

issue, the court would be required to interpret and then apply FFDCA statutory or regulatory provisions." *Mutual I*, 459 F. Supp. 2d at 934 (citing *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231 (3d Cir. 1990)); *see Cottrell*, 191 F.3d at 1255; *see also All One God Faith, Inc. v. The Hain Celestial Group, Inc.*, 2009 WL 4907433 (N.D. Cal. Dec. 14, 2009). "Simply put, the Lanham Act does not allow a federal court to determine preemptively how a federal agency will interpret and enforce its own regulations." *Summit Tech.*, 922 F. Supp. at 306 (citing *Sandoz Pharm. Corp.*, 902 F.2d at 231); *see Summit Tech., Inc. v. High-Line Med. Instruments, Co.* ("*Summit II*"), 933 F. Supp. 918, 933 (C.D. Cal. 1996) (refusing to allow a Lanham Act claim to proceed where the claim would force the court to rule directly on the legality of the defendant's conduct before the FDA had a chance to do so). This is especially true "in light of Congress' intention to repose in [the FDA] the task of enforcing the FDCA." *Braintree Lab., Inc. v. Nephro-Tech., Inc.* ("*Braintree*"), 1997 WL 94237, *6 (D. Kan. Feb. 26, 1997). "It is in this context that many courts have refused to allow a Lanham Act claim to proceed, as the alleged 'falsity' is not something that is verifiable without ... interpretation and application of FDA regulations." *Id.* at 936; *see also Sandoz Pharm. Corp.*, 902 F.2d at 231 (refusing to adjudge falsity of a cough syrup label when "the FDA ha[d] not found conclusively that [the product was mislabeled]" because doing so would require original interpretation of the FFDCA or its regulations). As the court in *Mutual I* concluded:

> If the allegedly false or misleading nature of the statement can be easily verified, then the fact that the determination of the truth of that statement was made by the FDA is immaterial

> so long as the party can also show the other requirements for establishing a Lanham Act claim, that is, that the false or misleading statement is likely to deceive consumers.

Mutual I, 459 F. Supp. at 935. In *American Home Products Corp. v. Johnson & Johnson*, the court similarly concluded that FDA approval was a defense to a competitor's Lanham Act claim. *American Home Prods. Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 145 (S.D.N.Y. 1987). The court held that "[i]f FDA approval of the precise label used by a drug manufacturer is a defense to a consumer's product liability action, it should be a *fortiori*, a defense to a competitor's action under the Lanham Act." *Id.*

"On the other hand, the simple fact that a matter touches upon an area dealt with by the FDA is not a bar to proceeding with a claim under the Lanham Act." *Ocean Spray*, 642 F. Supp. 2d at 1118 (citing *Mutual I*, 459 F. Supp. 2d at 935). For example, a Lanham Act claim may proceed where a plaintiff alleges that the defendant has affirmatively misrepresented compliance with FDA regulations, or where a court would only need to "verify whether defendant's specific label or conduct conforms to what the FDA has already determined is required." *Id.*; *see also Braintree*, 1997 WL 94237, *6 (holding that "[m]ost obviously, a false statement of FDA approval is sanctionable"); *see also Cytosport*, 2007 WL 1345379 at *2 (holding that "courts have refused to dismiss Lanham Act claims when plaintiffs can establish that the statements at issue are false or misleading without relying on the FDCA or FDA regulations"). To this end, preclusion of a Lanham Act claim will likely rest on "whether the false advertising involves a fact that can be easily verifiable, without requiring the truth of the fact to be determined by the

FDA." *Ocean Spray*, 642 F. Supp. 2d at 1118 (internal citation omitted).

Moreover, some courts have concluded that "false statements are actionable under the Lanham Act, even if their truth may be generally within the purview of the FDA." *Cytosport*, 2007 WL 1345379, at *2 (citing *Summit II*, 933 F. Supp. at 933); *see Cottrell*, 191 F.3d at 1256; As the court in *Summit Tech.* explained, "a plaintiff may bring a Lanham Act cause of action for affirmatively misrepresenting facts, even if the facts may be governed by FDA regulations." *Summit Tech.*, 922 F. Supp. at 307; *see also Pfizer, Inc.*, 868 F. Supp. at 449 (holding that literally false statements concerning areas of the FDA's purview can be actionable under the Lanham Act).

In *Grove Fresh Distributors, Inc. v. The Flavor Fresh Foods, Inc.*, the defendants sold orange juice labeled as "100% Orange Juice from Concentrate." *Grove Fresh*, 720 F. Supp. 714, 715 (N.D. Ill. 1989). The plaintiff sued under the Lanham Act, "asserting that because defendants' product was not 100% orange juice, its labeling was false and misleading." *Summit Tech.*, 922 F. Supp. at 307. The court found that plaintiff's claim was not an FFDCA cause of action "because, even without the FDA's orange juice definition, plaintiff could still establish a violation of [the Lanham Act]—indeed, the commercial definition of pure orange juice could be determined without *any* reference to FDA regulations." *Id.* The plaintiff could "rely on the FDA regulation merely to establish the standard or duty which [the] defendants allegedly failed to meet. Nothing prohibit[ed] [the plaintiff] from using the FDCA or its accompanying regulations in this fashion." *Id.* Likewise, in *Summit II*, the plaintiff argued that the defendant's imported products were improperly la-

beled because they were labeled as "identical" to domestically manufactured products that were FDA-approved. *Summit II*, 933 F. Supp. at 933. The court declined to dismiss the action because "the question of whether the domestic and international [products] are 'identical' is a factual one that can be resolved without the interpretation or application of FDA regulations." *Id.*

Similarly, in *Cytosport*, the court concluded that it would "not need to rely on the FFDCA or any FDA regulation to show that the statement 'Carb Conscious' is misleading." *Cytosport*, 2007 WL 1345379 at *3. Specifically, the court would not need to interpret or otherwise apply FFDCA or FDA regulations. *Id.* "To make its case, [the plaintiff] [could] present evidence, such as consumer surveys, that indicate consumers would consider such statement misleading when [the product] contains 15 grams of carbohydrate." *Id.* The court in *Mutual I*, therefore, concluded that it could distinguish between instances where courts "find either as a matter of common sense or normal English, that which the FDA, with all of its scientific expertise, has yet to determine ... [and instances where] the [FDA] should be given the first chance to exercise that discretion or to apply that discretion." *Mutual I*, 459 F. Supp. 2d at 938.

3. *Establishing Advertising under the Lanham Act Is Misleading*

Assuming a Lanham Act claim is not precluded by the FFDCA or FDA regulations, "in order to recover damages, ... the plaintiff must demonstrate that it has been damaged by actual consumer reliance on the misleading statements." *Emerging Material Tech., Inc. v. Rubicon Tech., Inc.*, 2009 WL 5064349, *4 (N.D.Ill. Dec.

14, 2009). Here, the statements-at-issue, namely Coca Cola's naming, labeling, advertising, and marketing, are not alleged to be literally false, but rather, misleading in context. Thus, "[w]here a statement is not literally false and is only misleading in context, ... proof that the advertising actually conveyed the implied message and thereby deceived a significant portion of the recipients becomes critical." *Mut. Pharm. Co. II*, 2009 WL 3401117 at *3 (citing *The William H. Morris Co. v. Group W, Inc.*, 66 F.3d 255, 258 (9th Cir. 1995)); *see Del Webb*, 2009 WL 3053709 at *13; *see Sandoz Pharm. Corp.*, 902 F.2d at 228-29 (context is important in evaluating the message conveyed); *see also Merck Consumer Pharm. Co. v. Smithkline Beecham Corp.*, 960 F.2d 294, 297-98 (2d Cir. 1992) (requiring plaintiff to demonstrate that a "statistically significant part of the commercial audience holds the false belief allegedly communicated by the challenged advertisement"). Indeed, "[e]ven if an advertisement is not literally false, relief is available under [the] Lanham Act § 43(a) if it can be shown that the advertisement has misled, confused, or deceived the consuming public." *Southland Sod Farms*, 108 F.3d 1134 at 1140.

"Reactions of the public are typically tested through the use of consumer surveys." *Southland Sod Farms*, 108 F.3d 1134 at 1140; *see also* J. Thomas McCarthy, *McCarthy on Trademarks and Unfair Competition* § 27:55 (4th ed. 1996) ("If the ad is not clear, plaintiff must produce evidence, usually in the form of market research or consumer surveys, showing exactly what message ordinary consumers received from the ad .... [T]he moving party must provide expert testimony or other evidence.") (internal citations omitted). "To assess the truth of [the] more amorphous, [or] misleading statements, the courts favor

testing by consumer reaction surveys, but have also found falsity based on their own independent reaction and the reaction of witnesses testifying before the court, including testimony based on test results, consumer surveys, complaints received, allegations of more than a few instances of misrepresentation and otherwise." *Cottrell*, 191 F.3d at 1252. In *Cottrell*, the Tenth Circuit concluded that "if [the plaintiff] can establish by consumer surveys or other means that [the defendant's] advertising is likely to confuse or actually confuses consumers, then the effect of the false 'implication' of EPA approval that [the plaintiff] now assumes could be as damaging for Lanham Act purposes as an express false claim of EPA approval." *Id.* at 1256; *see also Mut. Pharm. Co. II*, 2009 WL 3401117 at *3 (holding that the plaintiff did not need to rely on the FDCA or any FDA regulations in order to determine whether a statement was misleading, and instead, could "present evidence, such as consumer surveys, to indicate [that] consumers would consider [said] statement misleading"). However, "[t]o prove that use of [a] particular marketing channel conveys such a false impression ... [the plaintiff] cannot ... obtain relief by arguing how consumers could react; *it must be shown how consumers actually do react.*" *Mutual I*, 459 F. Supp. 2d at 940 (internal citations omitted) (emphasis added). Similarly, in *Sandoz*, the Third Circuit concluded:

> A Lanham Act plaintiff ... is not entitled to the luxury of deference to its judgment. Consequently, where advertisements are not literally false, plaintiff bears the burden of proving the actual deception by a preponderance of the evidence. Hence, [a plaintiff] cannot obtain relief by arguing how consumers could react; it must show how consumers actually do react ... The

> effect of the advertisement on the consumer is the critical determination, and it must be demonstrated by a Lanham Act plaintiff regardless of whether the claim is facially ambiguous.

Sandoz, 902 F.2d at 228-29. However, "[s]ubjective claims about products, which cannot be proven either true or false, are not actionable under the Lanham Act." (*Cytyc Corp. v. Neuromedical Sys., Inc.*, 12 F. Supp. 2d 296, 300 (S.D.N.Y. 1998)) (citing *Lipton v. Nature Co.*, 71 F.3d 464, 474 (2d Cir. 1995)), and "[a]s a general rule, summary judgment is inappropriate where an expert's testimony supports the nonmoving party's case." *Southland Sod Farms*, 108 F.3d at 1144.

In any event, the "failure to establish that a significant number of consumers [are] actually deceived is not necessarily fatal to [a plaintiff's] case. If [the defendant has] intentionally misled consumers, [the court will presume that] consumers were in fact deceived and [the defendant] would have the burden of demonstrating otherwise." *The William H. Morris Co. v. Group W, Inc.*, 66 F.3d 255, 258 (9th Cir. 1995); *see Del Webb*, 2009 WL 3053709 at *13; *see also Novartis Consumer Health, Inc. v. Johnson & Johnson*, 290 F.3d 578, 594 (3d Cir. 2002). Indeed, where a defendant "intentionally misl[eads]" consumers, by "deliberate conduct of egregious nature," courts may presume that consumers have been deceived. *William H. Morris Co.*, 66 F.3d at 258; *see also Gonzalez v. Allstate Ins. Co.*, 2005 WL 5891935, *10 (C.D. Cal. Aug. 2, 2005). Accordingly, even if Pom cannot establish by a preponderance of evidence that consumers were actually deceived by Coca Cola's allegedly misleading statements, if Pom can establish willful misconduct by Coca Cola, then the Court may presume that consumers have been deceived.

C. *The State Law Claims*

Since this Court's September 15, 2009 Order, several other courts in the Central District have addressed the issue of whether Pom has standing to assert similarly pled state law claims, and which the Court finds compelling. *See Pom Wonderful LLC v. Tropicana Products, Inc., et al.* ("*Tropicana*"), CV 09-00566 DSF (CTx) (C.D. Cal. Oct. 21, 2009); *Pom Wonderful LLC v. Welch Foods, Inc.* ("*Welch*"), CV 09-00567 AHM (AGRx), (C.D. Cal. Dec. 21, 2009). Specifically, to have standing under California Business & Professions Code § 17200, referred to as California's Unfair Competition Law ("UCL"), and California Business & Professions Code § 17500, referred to as California's False Advertising Law ("FAL"), Pom must show that it has suffered an injury in fact, namely that it has "lost money or property as a result of ... unfair competition." Cal. Bus. & Prof. Code §§ 17204, 17535. "[L]ost money or property" have been interpreted as requiring that a plaintiff show he is entitled to restitution from a defendant. *See Citizens of Humanity, LLC v. Costco Wholesale Corp.*, 171 Cal. App. 4th 1, 89 Cal. Rptr. 3d 455, 472 (2009) (holding that the alleged harm to a plaintiff's goodwill is not a loss of "money or property as a result of the unfair competition," and is insufficient to confer standing on the plaintiff); *see also Buckland v. Threshold Enterprises, Ltd.*, 155 Cal. App. 4th 798, 66 Cal. Rptr. 3d 543, 557-58 (2007) (holding that a plaintiff's purchase of goods which was made expressly in order to establish standing for an action in the public interest was "not reasonably viewed as lost money or property under the standing requirement").

In *Korea Supply Corp. v. Lockheed Martin Corp.*, the California Supreme Court held that for purposes of California's UCL, restitution is not "limited only to the

return of money or property that was once in the possession of that person." *Korea Supply Corp. v. Lockheed Martin Corp.*, 29 Cal. 4th 1134, 131 Cal. Rptr. 2d 29, 42, 63 P.3d 937 (2003). Specifically, the California Supreme Court held that "restitution is broad enough to allow a plaintiff to recover money or property in which he or she has a vested interest." *Id.* Thus, although earned "wages [can] be recovered as restitution under the UCL," a lost business opportunity, which is only an "attenuated expectancy interest," and not subject to a constructive trust, is not a vested interest, and cannot be recovered under the UCL as restitution. *Id.* The court further noted: "As the United States Supreme Court recently said, a constructive trust requires 'money or property identified as belonging in good conscience to the plaintiff [which can] clearly be traced to particular funds or property in the defendant's possession.'" *Id.* (citing *Great-West Life & Annuity Ins. Co. v. Knudson*, 534 U.S. 204, 213, 122 S. Ct. 708, 151 L. Ed. 2d 635 (2002)).

Here, it has been shown that Pom is not entitled to restitutionary relief. Specifically, it is clear that Pom has no vested share of the pomegranate juice market, or a vested interest in Coca Cola's profits from the Juice. As Judge Dale S. Fischer succinctly explained in *Tropicana*, "there is no reasonable definition of vested interest that would include market share." *Tropicana*, CV 09-00566, at 2. Similarly, Judge Howard A. Matz concluded that "like the plaintiff in *Korea Supply*, Pom seeks to recover nonrestitutionary disgorgement of profits that are nothing more than a 'contingent expectancy of a payment from a third party'—in this case, consumers." *Welch*, CV 09-00567, at 5 (citing *Korea Supply Corp.*, 131 Cal. Rptr. 2d at 42, 63 P.3d 937). Moreover, Pom is not entitled to seek injunctive relief

under the UCL and FAL, either. Indeed, as both Judge Dale S. Fischer and Judge Howard A. Matz noted, a restitutionary interest is required for standing, even if the plaintiff does not seek restitution as a remedy. *See Welch*, CV 09-00567, at 5; *see Tropicana*, CV 09-00566, at 2; *see Walker*, 558 F.3d at 1027. Because Pom's state law claims are strikingly similar to those it has pled in the above-mentioned cases, and because the Court finds Judge Howard A. Matz and Judge Dale S. Fischer's reasoning to be compelling, Coca Cola's summary adjudication as to this issue is GRANTED.

Accordingly, Coca Cola's Motion is **GRANTED IN PART** to the extent that Pom's state law claims are **DISMISSED**. Pom's Motion is **DENIED** as moot to the extent that it seeks to preclude Coca Cola's affirmative defenses against its state law claims.

D. *The Lanham Act Claim*

1. *Naming and Labeling*

Principally, Pom contends that Judge A. Howard Matz, Judge Dean D. Pregerson, and Judge Dale S. Fischer, as well as this Court, "all got it right at the motion to dismiss stage that federal law does not preclude or preempt Pom's claims against juice product naming and labeling." (Pl.'s Opp'n 2.) To that end, Pom seeks to have this Court indirectly require that Coca Cola change the Juice's naming and labeling to reflect what Pom believes is a more appropriate naming and/or labeling of the Juice's bottle. (FAC ¶ 20.) Pom states:

> Instead of calling its product "Apple Grape" juice, which are the two primary juices in its product, Coca Cola made a marketing decision to give this product the brand name "Pomegranate Blueberry" juice on the front label, and

> to juxtapose this brand name with a picture of a pomegranate and other fruits, among other misleading elements.

(FAC ¶ 20; Pl.'s Mot. 5.) Specifically, Pom alleges that Coca Cola's naming and labeling on the Juice's bottle is voluntary, and thus, Pom's claims are not directed at the features of the Juice's "formal" naming and labeling. (Pl.'s Opp'n 10; Pl.'s Mot. 5.) Pom argues therefore, that the Lanham Act claim is directed towards the Juice's naming and labeling, for "which [Coca Cola] chose in order to maximize the label's deceptive impact on consumers." (Pl.'s Opp'n 10.)

Coca Cola contends that the Juices name, "Pomegranate Blueberry Flavored Blend Of 5 Juices," "complies with all applicable FDA regulations," and so, is precluded from being challenged by the Lanham Act. Def.'s Mot. 8; *see* 58 Fed. Reg. 2897 at 2920; *see also* 21 C.F.R. § 102.33 (stating that "this revision of new § 102.33 along with the others discussed below are adequate to prevent misleading labels on multiple-juice beverages"). In support of its contention that the Juice's naming and labeling comport with the relevant FFDCA and FDA regulations, Coca Cola states that the Juice's "name includes two identified juices, pomegranate and blueberry. Because these named juices are not the predominant juices by volume, the product name includes the word 'flavored,' as required by 21 C.F.R. § 102.33(d), and as expressly permitted by 21 C.F.R. § 101.22(i)(1)(i), based upon the inclusion of 'natural flavors' in the Juice." (Def.'s Mot. 8.) Coca Cola further maintains that "because there are additional juices in the product, the [Juice's] name also includes the word 'blend,' as required by 21 C.F.R. § 102.33(c)." (Def.'s Mot. 8.)

This Court's previous Order held that Pom's Lanham Act claim against the Juice's formal name and label, "Pomegranate Blueberry Flavored Blend Of 5 Juices," "impermissibly challeng[es] the FDA's labeling for a multiple-juice beverage." (Order of Feb. 19, 2009). The FDA has directly spoken on the issues that form the basis of Pom's Lanham Act claim against the naming and labeling of the Juice, and has therefore, reached a conclusion as to what is permissible. *See* 21 C.F.R. §§ 102.33(c), (d). Indeed, the FDA has spoken on several occasions, and each time, it has concluded that manufacturers of multiple-juice beverages may identify their beverages with a non-primary, characteristic juice, as Coca Cola does here. *See* 56 Fed. Reg. 30452; *see* 58 Fed. Reg. 2897; *see Holk v. Snapple Beverage Corp.*, 574 F. Supp. 2d 447, 454 (D. New Jersey 2008), *cited with disapproval in Lockwood v. Conagra Foods, Inc.*, 597 F. Supp. 2d 1028, 1034 (N.D. Cal. 2009) ("the FDA under the broad authority granted to it by the FFDCA, has promulgated comprehensive regulations pertaining to, *inter alia*, ... the common or usual name for diluted multiple-juice beverages or a product containing a blend of single-strength juices ...."). The rules promulgated by the FDA are intended to protect the public from unsafe or mislabeled products by setting forth federal labeling requirements, and with which the Juice's naming and labeling comply. *Wyeth v. Sun Pharm. Indus., Ltd.*, 2010 WL 746394 (E.D. Mich. Mar. 2, 2010) (citing *Wyeth v. Levine*, 555 U.S. 555, 129 S. Ct. 1187, 1195, 173 L. Ed. 2d 51 (2009)). Thus, the name "Pomegranate Blueberry Flavored Blend Of 5 Juices" sufficiently comports with the requirements of 21 C.F.R. §§ 102.33(c), (d).

Moreover, although the Juice's name appears in different fonts and on different lines, Pom has not provid-

ed the Court with evidence that the Juice's naming and labeling is not prominently displayed, and so not in compliance with 21 U.S.C. § 343(f).[21] *See Wyeth v. Levine*, 129 S. Ct. at 1197 ("The FDCA does not provide that a drug is misbranded simply because the manufacturer has altered an FDA-approved label; instead, the misbranding provision focuses on the substance of the label and, among other things, proscribes labels that fail to include 'adequate warnings.' "); *see Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 823-24, 106 S. Ct. 3229, 92 L. Ed. 2d 650 (1986) ("a drug is 'misbranded' under the FDCA if 'the labeling or advertising *fails to reveal facts material* ... with respect to consequences which may result from the use of the article to which the labeling or advertising relates.' ") (emphasis added) (internal citations omitted); *see Mensing v. Wyeth, Inc.*, 588 F.3d 603, 611 (8th Cir. 2009) (holding that the misbranding provisions of the FDCA, 21 U.S.C. § 355(e), "focus on the accuracy of a product's label"); *see also* 21 U.S.C. § 352(f). Pom has not shown that the Juice's name must appear on one single line, must be in one font, or must be centrally located on the Juice's bottle, in order to avoid being branded mislabeled, or that as a consequence of these aesthetic features, the Juice's naming and labeling is not prominently displayed. *See* 21 U.S.C. § 343(f); *see generally* Pl.'s Opp'n; *see* 58 Fed.

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[21] 21 U.S.C. § 343(f), entitled "Prominence of information on label," provides: "If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not *prominently placed* thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use." 21 U.S.C. § 343(f) (emphasis added).

Reg. 2897, at 2902-03; *see also Braintree*, 1997 WL 94237, *6. Instead, all that 21 U.S.C. § 343(f) requires is that Coca Cola prominently place the label on the Juice's bottle, and which Coca Cola does sufficiently. *See* 21 U.S.C. § 343(f).

In any event, any such determination that naming and labeling must be displayed in a particular way or fashion, as Pom suggests, would necessarily be for the FDA to determine, and so, is not for this Court to construe or interpret. *See Braintree*, 1997 WL 94237 at *6. Thus, because "Pomegranate Blueberry Flavored Blend Of 5 Juices" complies with the relevant FDA regulations and is prominently displayed on the Juice's front panel, pursuant to 21 U.S.C. § 343(f), even if not to the liking of Pom, this Court cannot conclude that the Juice's naming and labeling is misleading, inaccurate, or outside the purview of the FDA.

Of course, "Pom is free to lobby Congress or petition FDA to change its rules ...." Def.'s Opp'n 2; *see also American Home Prods. Corp.*, 672 F. Supp. at 145 ("If the intercession of a private attorney general is needed to press the FDA to perform that duty with respect to a particular product label, the quickest and most effective relief could be obtained through a direct petition to the agency and not through an unfair competition action against the manufacturer ... There is no apparent reason why [the plaintiff] cannot ask the FDA to reconsider that approval in light of the survey evidence it has presented here to show the message users take from ... [the defendant's] package.") As a private litigant, Pom cannot seek to have this Court indirectly attack FDA regulations as courts may not be used to

second-guess the considered judgments of the FDA.[22] *Cytyc*, 12 F. Supp. 2d at 301 (concluding that FDA approval of statements is a defense to a competitor's Lanham Act claim). Coca Cola may name the Juice a blend or a flavor since such language is expressly permitted (required here) by the FDA, even if pomegranate and/or blueberry are merely characteristic, rather than primary juices in the Juice. *See* 21 C.F.R. §§ 102.33(c), (d). Pom's challenge to the Juice's name and label, "Pomegranate Blueberry Flavored Blend Of 5 Juices," on the Juice's bottle, is therefore, barred. *Id.*

Accordingly, because Coca Cola's naming and labeling of the Juice comports with the relevant FFDCA and FDA regulations, Coca Cola's Motion is **GRANTED IN PART** to the extent that Pom is precluded from pursuing its Lanham Act claim against the naming and labeling on the Juice's bottle. Similarly, Pom's Motion is **DENIED** as moot to the extent that Pom seeks to bar Coca Cola from presenting evidence that the Juice's naming and labeling comply with FDA regulations.

2. *The Fruit Vignette*

Pom contends that the imagery on the Juice's bottle's front panel, which includes the Fruit Vignette, in-

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[22] Pom argues that *Cytyc* is distinguishable from the facts of this case because the FDA has not expressly approved of the Juice's naming or labeling. (Pl.'s Opp'n 12.) However, the Court finds *Cytyc* compelling because the court in *Cytyc* similarly dealt with "statements that [did] not correspond precisely to statements that the FDA ha[d] approved." *Cytyc*, 12 F. Supp. 2d at 301. In any event, the court concluded that "the challenged statements discussed above [were] similar enough to the approved statements for the court to conclude, as a matter of law, that they are neither false not misleading." *Id.*

tentionally misleads consumers. (Pl.'s Opp'n 11; Def's Statement in Opp'n ¶ 2.) Specifically, because the centrally-placed Fruit Vignette includes a large half-open pomegranate, Pom argues that consumers will incorrectly believe that the Juice consists primarily of pomegranate juice. (Pl.'s Opp'n 11; Torrey Decl. Ex. 1; Def's Statement in Opp'n ¶ 2.) In response, Coca Cola contends that because the Fruit Vignette complies with FDA regulations, Pom is necessarily precluded from alleging that the Fruit Vignette violates the Lanham Act. (Def.'s Mot. 8.)

In the FDA's 1993 Final Rules, whereby the FDA discussed the depiction of fruits on a label vignette, the FDA expressed the belief that vignettes depicting pictures of the fruit or vegetable sources of all juices present in a product would be useful to consumers, and so encouraged manufacturers to use vignettes. *See* 58 Fed. Reg. 2897 at 2918-21; *see Ocean Spray*, 642 F. Supp. 2d at 1119-20. The fact that the FDA discussed vignettes within the context of juice labels suggests that vignettes are related to and/or part of a juice's label. Specifically, the FDA stated that "a vignette that pictures only some of the fruit or vegetables in the beverage would not be misleading where the name of the food adequately and appropriately describes the contribution of the pictured juice." *See* 58 Fed. Reg. 2897 at 2918-21. Indeed, it is generally a juice's name, as well as the vignette, that instructs consumers as to what a juice contains. Thus, it would be inconsistent, if not nonsensical, for the FDA to say that a determination of whether a juice's naming and labeling is misleading depends on the interplay between a juice's naming and labeling, and any accompanying vignette, but that it, nonetheless, declines to regulate such vignettes. Rather, because vignettes are intricately related to a de-

termination of whether a juice label and/or name is misleading, vignettes, like the Fruit Vignette, are within the FDA's purview.

To that end, the example used by the FDA in its 1993 Final Rules indicates that the Fruit Vignette clearly complies with FDA requirements relating to the depiction of vignettes. *See* 58 Fed. Reg. 2897 at 2918-21. Specifically, the FDA indicated that for a "100 percent juice product consisting of apple, grape, and raspberries, in which the raspberry juice provides the characterizing flavor," it would not be misleading if the vignette depicts only raspberries, as long as "the statement of identity [is] 'raspberry juice in a blend,' or 'raspberry juice in a blend of two other juices, 3 to 8 percent raspberry juice.' " *See* 58 Fed. Reg. 2897 at 2918-21. Here, the Juice is identified as a "Blend," such that Coca Cola's statement of identity adequately and appropriately identifies pomegranate and blueberry as merely characterizing flavors. Thus, because the Fruit Vignette in fact depicts all of the juices in the Juice, as opposed to only "some" of the juices (i.e., blueberries and/or pomegranates), Coca Cola has seemingly provided more information and identification for consumers than is even required by the FDA. Pursuant to the FDA's 1993 Final Rules, the Fruit Vignette is, therefore, clearly not misleading.

Subsequent to the FDA's 1993 Final Rules, a handful of courts have looked at whether the FDA is tasked with regulating fruit vignettes on products, and in each instance, the court has concluded that the regulation of vignettes comes within the FDA's purview. *See R. McKinnis v. Kellogg, USA*, 2007 WL 4766060, *4 (C.D. Cal. Sept. 19, 2007); *see Holk v. Snapple Beverage*

Corp., 574 F. Supp. 2d at 454.[23] Although *R. McKinnis* pertains to state law claims, and so is distinguishable from the facts before this Court, *R. McKinnis* concluded that fruit vignettes are FDA-regulated:

> For one, the depiction of fruit on a product label is not a specific affirmation that a product contains any fruit at all. *FDA regulations permit illustrations of fruit on product label[s]* to indicate that product's 'characterizing flavor,' even where the product contains no ingredients derived from the depicted fruit .... Froot Loops contains 'ALL NATURAL FLAVORS' of lime, orange, lemon, cherry, raspberry, and blueberry, as disclosed in the ingredients panel, rendering any depiction of fruit 'vignettes' on the box entirely accurate and permissible under FDA regulations.

R. McKinnis, 2007 WL 4766060 at *4 (emphasis added).

Accordingly, because the depiction of vignettes on multi-juice beverages is an area of regulation within the FDA's purview, as the FDA's 1993 Final Rules and subsequent caselaw reflect, and because the Fruit Vi-

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[23] Although the court in *Holk* concluded that the "FDA, under the broad authority granted to it by the FFDCA, has promulgated comprehensive regulations pertaining to ... (4) label depictions by 'vignette or other pictorial representation' on products," *Lockwood* expressly stated that it was "not persuaded by [*Holk*]." *See Lockwood*, 597 F. Supp. 2d at 1034; *see Holk*, 574 F. Supp. 2d at 454. In any event, the Court cites *Holk* because it is one of only a few courts that has directly dealt with the issue of whether vignettes come within the purview of the FDA, and because *Lockwood* did not expressly or directly conclude that fruit vignettes are outside the purview of the FDA. *See Lockwood*, 597 F. Supp. 2d at 1034. Rather, *Lockwood* merely indicated that the FDA's reach is not as extensive or as exhaustive as *Holk* concluded. *Id.*

gnette is clearly not misleading pursuant to the FDA's 1993 Final Rules, Coca Cola's Motion is **GRANTED IN PART** to the extent that Pom is precluded from pursuing its Lanham Act claim against the Fruit Vignette. Similarly, Pom's Motion is **DENIED** as moot to the extent that Pom seeks to bar Coca Cola from presenting evidence that the Fruit Vignette complies with FDA regulations.

3. *Advertising and Marketing*

a. Consumer Confusion

This Court previously concluded that Pom is not prevented from alleging that Coca Cola "has otherwise advertised and marketed [the Juice] in a misleading manner ..." (Order of Sept. 15, 2009.) Coca Cola "fully accepts, and does not contest ... that advertising apart from the Juice's formal name and label is subject to challenge under [the] Lanham Act." (Def.'s Mot. 14.) As such, it is critical that Pom show "proof that the advertising actually conveyed the implied message and thereby deceived a significant portion of the recipients." *The William H. Morris Co.*, 66 F.3d at 258. As in *Gonzalez*, whether Coca Cola's advertising and marketing has a tendency to deceive a substantial segment of the relevant audience is a disputed question of fact. *Gonzalez*, 2005 WL 5891935, *9.

"The party offering a survey as proof of consumer confusion bears the burden of proving its reliability." *Pfizer, Inc.*, 868 F. Supp. at 447. To that end, Pom alleges that "[t]he 35% differential which the Field Survey found between the test and control groups' respective belief that the Juice only contains pomegranate and blueberry juice far exceeds the percentage that district courts typically find acceptably for a consumer survey in support of a Lanham Act claim." Decl. of

Steven A. Zalesin ("Zalesin Decl.") Ex. 1; Pl.'s Opp'n 5; *see Novartis Consumer Health, Inc.*, 290 F.3d at 594 (finding that 15.5% would be sufficient to support a finding of substantial consumer confusion). The Field Survey provides some evidence of consumer deception. (Zalesin Decl. Ex. 1.) Pom contends that the Field Survey directly demonstrates the generally misleading effect that the Juice has on consumers, such that consumers are likely "to believe that the Juice *mainly* contains pomegranate and blueberry juice (and not other types of fruit juice)." (Zalesin Decl. Ex. 1; Pl.'s Addt'l SOF ¶¶ 32-33.)

Coca Cola "hotly disputes the methodology and conclusions of [the Field Survey]." (Def.'s Mot. 17; Decl. of Dr. Ran Kivetz in Supp. of Def.'s Mot. for Summ. J. ("Kivetz Decl.") ¶ 2.) Coca Cola argues that "Pom has not identified a shred of evidence that any of [Coca Cola's] ads are false or misleading in any respect," and so "Pom has offered no evidence that [Coca Cola's] website or ads have misled consumers." (Def.'s Mot. 14; Def.'s Reply 5.) As such, Coca Cola contends that because the Field Survey fails to address Coca Cola's advertising or marketing, and instead, only addresses the Juice's name and label, it is "unreliable." (Def.'s Reply 3; Kivetz Decl. ¶ 3, Ex. A.) Specifically, Coca Cola states that "[t]he only stimulus shown to the survey participants was the bottle and label of the Juice," and so the Field Survey "did not attempt to evaluate the messages conveyed by the Juice's website of any of [Coca Cola's] other advertising." (Def.'s Mot. 3-4; *see generally* Kivetz Decl. Ex. A.)

The Ninth Circuit holds that "surveys in trademark cases are to be admitted as long as they are conducted according to accepted principles ... [Moreover,] [t]echnical reliability goes to the weight accorded a

survey, not its admissibility." *CKE Rest.*, 494 F. Supp. 2d at 1144 (citing *E.J. Gallo Winery v. Gallo Cattle Co.*, 967 F.2d 1280, 1292 (9th Cir. 1992)); *see also Pfizer, Inc.*, 868 F. Supp. at 447 ("The probative value of a survey depends entirely upon its fundamental fairness and objectivity, which in turn depends on many factors, such as whether it is properly 'filtered' to screen out those who got no message from the advertisement, whether the questions are directed to the real questions, and whether the questions are leading or suggestive."). Furthermore:

> The weight and evidentiary value of a survey's results rest upon the underlying objectivity of the survey itself. This objectivity, in turn, depends upon many factors, such as whether [the survey] is properly filtered to screen out those who got no message from the advertisement whether the questions are directed to the real issues, and whether the questions are leading or suggestive.

CKE Rest., 494 F. Supp. 2d at 1144 (citing *Johnson & Johnson Merck Consumers v. Smithkline Beecham Corp.*, 960 F.2d 294, 300 (2d Cir. 1992)). Any deficiencies cited by Coca Cola regarding the Field Survey, therefore, "weaken the relevance and credibility of the survey evidence." *CKE Rest.*, 494 F. Supp. 2d at 1144. Accordingly, the Field Survey is seemingly unreliable for the reasons articulated by Defendant. In particular, the Field Survey does not appear to relate to Coca Cola's advertising and marketing, and only implicates the naming and labeling of the Juice bottle. (Jay Decl. Ex. A.) However, whether the Field Survey actually meets the *Daubert* standards is best considered at trial.

b. Willful Deception

In any event, even if the Field Survey is defective as to the advertising and marketing claim, if Pom has other evidence of consumer deception, or if Pom can show that Coca Cola intentionally misled consumers, the burden may shift to Coca Cola to demonstrate otherwise. *See The William H. Morris Co.*, 66 F.3d at 258.

Coca Cola, however, contends that Pom cannot "circumvent the consumer survey requirement by arguing that [Coca Cola's] false advertising is 'willful' and 'thus inherently establishes that consumers are substantially deceived.' " (Def.'s Reply 4; Pl.'s Opp'n 18.) Coca Cola argues that Pom's evidence of alleged "willful deception" does not relate to its website or advertisements for the Juice. (Def.'s Reply 4-5.) First, Coca Cola states that the Reid correspondence, referred to by Pom as a "smoking gun," relates solely to the Juice's name, not its advertising, marketing, or website. (Def.'s Reply 5.) Coca Cola further notes that the Reid correspondence illustrates Coca Cola's desire to comply with FDA regulations, and so, does not evidence an egregious or willful intent to deceive. (Def.'s Reply 5.) Finally, Coca Cola argues that the consumer complaints cited by Pom are based on consumers who bought the Juice in stores, not consumers who viewed the website or Coca Cola's other advertising media. (Def.'s Reply 5.)

Coca Cola's claims are seemingly meritorious. However, the Court concludes that Pom should have the opportunity to demonstrate otherwise. Accordingly, drawing all inferences in favor of Pom as this Court must, the Court concludes that triable issues of material fact remain as to Pom's advertising and marketing claims.

III. *RULING*

For the foregoing reasons, Coca Cola's Motion is **GRANTED IN PART** and **DENIED IN PART**, and Pom's Motion is **DENIED**.

IT IS SO ORDERED.

APPENDIX E

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES—GENERAL

CASE NO.: CV 08-06237 SJO (FMOx)
DATE: September 15, 2009

TITLE: POM Wonderful LLC v. The Coca Cola Company

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PRESENT: THE HONORABLE S. JAMES OTERO, UNITED STATES DISTRICT JUDGE

Victor Paul Cruz	Not Present
Courtroom Clerk	Court Reporter

COUNSEL PRESENT FOR PLAINTIFF:

Not Present

COUNSEL PRESENT FOR DEFENDANT:

Not Present

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PROCEEDINGS (in chambers): ORDER DENYING DEFENDANT'S MOTION TO DISMISS FIRST AMENDED COMPLAINT PURSUANT TO FED. R. CIV. P. 12(b)(6)
[Docket No. 55]

This matter is before the Court on Defendant The Coca Cola Company's ("Coca Cola") Motion to Dismiss First Amended Complaint Pursuant to Fed. R. Civ. P. 12(b)(6), filed August 10, 2009. This Court held a hear-

ing on September 8, 2009. (*See* Order of Sept. 9, 2009.) For the following reasons, the Court DENIES Coca Cola's Motion to Dismiss.

I. BACKGROUND

Plaintiff Pom Wonderful ("Pom") produces, markets, and sells POM WONDERFUL® brand bottled pomegranate juice and various pomegranate juice blends, including a pomegranate blueberry juice blend. (Compl. ¶ 11.) Coca Cola, under the brand Minute Maid,® is one of Pom's primary competitors in the bottled pomegranate juice market. (Compl. ¶ 17.) In September 2007, Coca Cola announced a new product in its "Minute Maid® Enhanced Juices" line, called "Minute Maid® Enhanced Pomegranate Blueberry Flavored 100% Juice Blend"[1] (the "Juice"). (Compl. ¶ 18.)

Pom alleges that "the main ingredients in [the Juice] are neither pomegranate nor blueberry juice, but rather, apple and grape juice." (Compl. ¶ 19.) Specifically, in ranking the ingredients of the Juice by volume, apple juice ranks first, grape juice ranks second, pomegranate juice ranks third, and blueberry juice ranks fifth. (Compl. ¶ 22.) Nevertheless, Coca Cola labels the Juice as "Pomegranate Blueberry" juice and advertises

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[1] Coca Cola takes issue with the Complaint's consistent reference to the product at issue as "Pomegranate Blueberry" without using the full name of the product, "Pomegranate Blueberry Flavored Blend of 5 Juices," as printed on the label featured in the Complaint. (*See* Compl.; *see generally* Mot. to Dismiss Pursuant to Fed. R. Civ. P. 12(b)(6) ("Def.'s Mot.") 2.)) The Court notes that Exhibit B to the Complaint is a depiction of the Minute Maid® website, which shows that Coca Cola does—at least on occasion—refer to the product as "Pomegranate Blueberry" without including the phrase "Flavored Blend of 5 Juices." The Court will therefore refer to the product at issue as "the Juice" to avoid the conflict between the parties over its proper name. (*See* Compl., Ex. B.)

and markets the Juice, through its packaging, commercials, Minute Maid's website, and other forms of advertising, "based on the representation that [its] primary ingredients ... are pomegranate and blueberry juice, when, in fact, the primary ingredients are actually apple and grape juice." (Compl. ¶¶ 8, 20.) As such, Pom alleges that purchasers of the Juice "are likely to be misled and deceived by Coca Cola's ... labeling, marketing and advertising," which damages not only the consuming public, but also Pom as Coca Cola's competitor. (Compl. ¶¶ 22-26.)

Based on these allegations, Pom filed this action against Coca Cola in September 2008 alleging claims for: (1) false advertising under the Lanham Act, § 43(a), 15 U.S.C. § 1125(a); (2) false advertising under California Business and Professions Code § 17500 *et seq.*; and (3) statutory unfair competition under California Business and Professions Code § 17200 *et seq.* (*See* Compl. ¶¶ 1, 27-48.) Coca Cola then moved to dismiss all claims pursuant to Federal Rule of Civil Procedure 12(b)(6) on November 26, 2008. (*See* Def.'s Mot. 2.) This Court granted in part and denied in part Coca Cola's motion to dismiss (*See* Order of Feb. 10, 2009).

On April 15, 2009, Pom served discovery on Coca Cola, but Coca Cola objected to and refused to respond to all discovery with respect to the naming, labeling, and packaging of the Juice. (*See* Pl.'s Mem. P. & A. Opp'n to Def.'s Mot. to Dismiss First Am. Compl. ("Pl.'s Mem") 1) As such, Pom filed a First Amended Complaint ("FAC") on July 27, 2009 to clarify the scope of this Court's previous order. (*See generally* Pl.'s FAC) The FAC alleges claims for: (1) false advertising under the Lanham Act, 15 U.S.C. § 1125(a); (2) false advertising under California Business and Professions Code § 17500 *et seq.*; and (3) statutory unfair competi-

tion under California Business and Professions Code § 17200 *et seq.* (*See generally* FAC.) In response, Coca Cola filed a Motion to Dismiss First Amended Complaint on August 10, 2009. (*See* Mot. To Dismiss First Am. Compl. Pursuant to Fed. R. Civ. P. 12(b)(6) ("Def.'s Mot. to Dismiss FAC").)

II. DISCUSSION

A. Pom is Not Precluded From Discovery in Furtherance of Its Lanham Act Claim.

The Court's previous order made it clear that "Pom's entire Lanham Act claim is not barred because the Juice, as a multiple-juice beverage, is an FDA-regulated product." (*See* Order of Feb. 10, 2009.); *see Mutual Pharm. Co.*, 459 F.Supp.2d at 933 (internal citations omitted); *see also Ethex Corp.*, 228 F. Supp. 2d at 1055; *Summit Tech, Inc.*, 933 F. Supp. at 933. Specifically, FDA juice-naming and labeling regulations do not bar Pom from alleging that Coca Cola has advertised or marketed the Juice in a misleading manner on its website and in other advertising avenues, thereby leading consumers to wrongly believe that the Juice's primary ingredients are pomegranate and blueberry. (*See* Order of Feb. 10, 2009.) Coca Cola, however, has interpreted the scope of this Court's prior order as suggesting that Pom is barred from pursuing its Lanham Act claim. (*See* Def.'s Mot. to Dismiss FAC.) This interpretation is incorrect.

It remains unclear whether Coca Cola's website is formal naming and labeling, or whether, as Pom asserts, Coca Cola's website functions as an advertisement, in which case Pom's Lanham Act claim is clearly not barred. (*See* Order of Feb. 10, 2009.) In particular, in various avenues, Coca Cola has placed a "prominent image of a split open pomegranate" next to the Juice

name, and advertised the Juice on its website as "cranberry and pomegranate juice." (*See* Pl.'s Mem. of P. & A. in Opp'n to Def.'s Mot. to Dismiss ("Pl.'s Opp'n") 7.) These informal cues suggest advertising and marketing, which may implicate the Lanham Act. Additionally, if Coca Cola's website's names or labels for the Juice are informal, they may not be expressly regulated by the FDA. (*See* Order of Feb. 10, 2009.) Indeed, informal naming and labeling do not necessarily implicate FDA regulations. (*See* Order of Feb. 10, 2009.) Accordingly, at this early stage Pom is entitled to conduct discovery to determine to what extent Coca Cola's various cues can be identified as naming and labeling, or as advertising and marketing. (*See generally* Order of Feb. 10, 2009.)

The subject of this Court's previous order was recently addressed by Judge Matz, which was discussed when the parties appeared before the Court on September 8, 2009. *See Pom Wonderful LLC v. Welch Food, Inc.*, No. CV 09-00567 (C.D. Cal. June 23, 2009); *see generally* (Order of Sept. 9, 2009.) Judge Matz suggested that if implicated FDA regulations are not technical, there is little risk to the court of being required to interpret them de novo. "Put another way, Pom could establish that Welch's labeling is misleading even if the FDA regulations set mandatory standards for when a beverage may include an image of a fruit on the label." *See Pom Wonderful LLC v. Welch Food, Inc.*, No. CV 09-00567. This Court noted that the matter before Judge Matz is factually similar to this action. (*See* Order of Sept. 8, 2009.)

Judge Pregerson also weighed in on this issue in *Pom Wonderful LLC, v. Ocean Spray Cranberries, Inc.*, holding that Defendant's "allegation of marketing representations does not directly or indirectly usurp

the FDA's role, because determining the primary ingredients of the beverage and whether Defendant's representations are misleading is not contingent on a decision of fact by the FDA or the enforcement of its regulations." *Pom Wonderful LLC*, 2009 WL 2151355 (C.D. Cal. 2009). Indeed, this action is factually similar to the matter before Judge Pregerson, also.

This Court therefore reasserts its previous position, which is that Pom is not barred from alleging that Coca Cola "has otherwise advertised and marketed its product in a misleading manner that leads consumers to believe that the primary ingredients are pomegranate and blueberry." (*See* Order of Feb. 10, 2009.) Indeed, at this motion to dismiss stage it is unnecessary to demarcate and identify which (if any) of the allegations in the FAC are within the FDA's sole purview, and which allegations are encompassed by the Lanham Act. *See generally Pom Wonderful LLC*, 2009 WL 2151355 (C.D. Cal. 2009). Accordingly, Pom is permitted to conduct discovery with respect to the naming, labeling, and packaging of the Juice.

B. Pom Has Standing to Assert Its State Law Claims

Coca Cola claims that Pom lacks standing to bring its state law claims under California's Unfair Competition Law ("UCL"). Simply put, Coca Cola alleges that Pom has no vested interest in the proceeds of the Juice and so Pom's claim fails because standing is a threshold issue. *See Walker v. Geico Gen. Ins. Co.*, 558 F.3d 1025, 1027 (9th Cir. 2009) (holding that "the UCL in § 17204 now requires a plaintiff to establish that it has 'suffered injury in fact and has lost money or property' ... [T]he import of the requirement is to limit standing to individuals who suffer losses of money or property that are

eligible for restitution."). However, pursuant to *Korea Supply Co. v. Lockhead Martin Corp.*, "restitutionary disgorgement is available under UCL." *Korea Supply Co.*, 29 Cal.4th 1134 (2003).

Pom alleges that its lost market shares constitute the loss of a vested interest for purposes of UCL claims, so that restitutionary relief remains available here. *Overstock.com, Inc. v. Gradient Analytics, Inc.*, 151 Cal. App.4th 688, 716 (2007). Pom is therefore permitted to establish that its interest, Coca Cola's profits, can "be traced to ill-gotten funds," which would therefore be a "vested" interest and entitle Pom to restitution. *Cumis Insurance Society v. Merrick Bank Corp.*, 2008 WL 427787, at 6* (D. Ariz. Sept. 18, 2008). As such, the Court concludes that Pom has standing to pursue its state law claims.

Accordingly, Coca Cola's Motion is DENIED. Pom may pursue discovery in furtherance of its Lanham Act claim and Pom's state law claims are not barred for lack of standing.

Defendant has until **September 30, 2009** to answer the Complaint.

IT IS SO ORDERED.

APPENDIX F

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

POM WONDERFUL LLC,
Plaintiff,

v.

THE COCA COLA COMPANY,
Defendant.

No. CV 08-06237 SJO (JTLx)
Feb. 10, 2009

ORDER GRANTING IN PART, DENYING IN PART DEFENDANT'S MOTION TO DISMISS PURSUANT TO FED. R. CIV. P. 12(b)(6) [Docket No. 8]

S. JAMES OTERO, District Judge.

This matter is before the Court on Defendant The Coca Cola Company's ("Coca Cola") Motion to Dismiss Pursuant to Fed. R. Civ. P. 12(b)(6), filed November 26, 2008. Plaintiff Pom Wonderful LLC ("Pom") filed an Opposition, to which Coca Cola replied. The Court found this matter suitable for disposition without oral argument and vacated the hearing set for January 5, 2009. *See* Fed. R. Civ. P. 78(b). For the following reasons, Coca Cola's Motion is **GRANTED IN PART, DENIED IN PART.**

I. *BACKGROUND*

Pom produces, markets, and sells POM WONDERFUL® brand bottled pomegranate juice and various pomegranate juice blends, including a pomegranate

blueberry juice blend. (Compl.¶ 11.) Coca Cola, under the brand Minute Maid, is one of Pom's primary competitors in the bottled pomegranate juice market. (Compl.¶ 17.) In September 2007, Coca Cola announced a new product in its "Minute Maid Enhanced Juices" line, called "Minute Maid® Enhanced Pomegranate Blueberry Flavored 100% Juice Blend."[1] ("the Juice"). (Compl.¶ 18.)

Pom alleges that "the main ingredients in [the Juice] are neither pomegranate nor blueberry juice, but rather, apple and grape juice." (Compl.¶ 19.) Specifically, in ranking the ingredients of the Juice by volume, apple juice ranks first, grape juice ranks second, pomegranate juice ranks third, and blueberry juice ranks fifth. (Compl.¶ 22.) Nevertheless, Coca Cola labels the Juice as "Pomegranate Blueberry" juice and advertises and markets the Juice, through its packaging, commercials, Minute Maid's website, and other forms of advertising, "based on the representation that [its] primary ingredients ... are pomegranate and blueberry juice, when, in fact, the primary ingredients are actually apple and grape juice." (Compl.¶¶ 8, 20.) As such, Pom alleges that purchasers of the Juice "are likely to be misled and deceived by Coca Cola's ... labeling, market-

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[1] Coca Cola takes issue with the Complaint's consistent reference to the product at issue as "Pomegranate Blueberry" without using the full name of the product, "Pomegranate Blueberry Flavored Blend of 5 Juices," as printed on the label featured in the Complaint. (*See generally* Compl. & Compl., Ex. A.; Def.'s Mot. n. 1.) Although the Court notes that Exhibit B to the Complaint, a depiction of Minute Maid's website, shows that Coca Cola does—at least on occasion—refer to the product as "Pomegranate Blueberry" without including the phrase "Flavored Blend of 5 Juices," the Court will refer to the product at issue as "the Juice" to avoid the conflict between the parties over its proper name. (*See* Compl., Ex. B.)

ing and advertising," which damages not only the consuming public but also Pom as Coca Cola's competitor. (Compl.¶¶ 22-26.)

Based on these allegations, Pom brought suit against Coca Cola, alleging claims for (1) false advertising under the Lanham Act, 15 U.S.C. § 1125(a); (2) false advertising under California Business and Professions Code § 17500; and (3) statutory unfair competition under California Business and Professions Code § 17200. (*See* Compl. ¶¶ 27-48.) Coca Cola now moves to dismiss all claims pursuant to Federal Rule of Civil Procedure 12(b)(6). (*See* Mot. Dismiss Pursuant to Fed. R. Civ. P. 12(b)(6) ("Def.'s Mot.") 2.)

II. *DISCUSSION*

A. *Lanham Act Claim*

Coca Cola argues that Pom's Lanham Act claim should be dismissed because the claim is merely an impermissible circuitous route to challenge determinations of the FDA, as the name of the Juice conforms to applicable juice-naming statutory and regulatory requirements featured in the Federal Food, Drug, and Cosmetic Act ("FFDCA") and its implementing regulations promulgated by the FDA. (*See* Def.'s Mot. 7-8.) In opposition, Pom contends that Coca Cola's misleading statements are actionable under the Lanham Act, because its Lanham Act claim does not depend in any way on violations of the FFDCA or FDA regulations and established authority permits Lanham Act claims involving FDA-regulated products to proceed as long as the court is not required to interpret or give original definition to FDA regulations. (*See* Pl.'s Opp'n Def.'s Mot. Dismiss Pursuant Fed. R. Civ. P. 12(b)(6) ("Pl.'s Opp'n") 4-9.)

Both the Lanham Act and the FFDCA regulate the marketing of various products, including juice beverages, but each statute "serves different, although somewhat overlapping, purposes." *See* 15 U.S.C. § 1125(a); 21 U.S.C. § 343; *Mutual Pharm. Co. v. Ivax Pharms., Inc.*, 459 F. Supp. 2d 925, 933 (C.D. Cal. Oct. 17, 2006). The central focus of the Lanham Act is to prevent false or misleading representations in promoting a product in the marketplace. *See Mutual Pharm. Co.*, 459 F. Supp. 2d at 932. As such, "the Lanham Act is primarily intended to protect commercial interests from being harmed by the unfair competition created by a competitor ... using false or misleading advertising" to promote its products. *Id.* at 933 (internal citations and quotations omitted). Consistent with this purpose, the Lanham Act expressly establishes a private right of action, allowing a private plaintiff to sue as a result of harm from a competitor's false or misleading advertising. *See* 15 U.S.C. § 1125(a); *Mutual Pharm. Co.*, 459 F. Supp. 2d at 933. In contrast, the FFDCA is focused on protecting the public by ensuring that goods sold in the marketplace are safe and not misbranded. *See id.* Unlike the Lanham Act, the FFDCA and its implementing FDA regulations may not be privately enforced, as the right to enforce the FFDCA "lies exclusively in the federal government's domain, by way of either the FDA or the Department of Justice." *Id.* at 934 (internal citations omitted); *see* 21 U.S.C. § 337. As another court in the Central District of California has explained,

> That the statutes may regulate the same market should not be seen as necessarily requiring that application of one be at the sufferance of the other .... Where the statutes overlap they perform different, but complementary roles to regulate what products can make it to market

> ([F]FDCA), and how those products are then promoted in the market (the Lanham Act and to a certain extent the [F]FDCA through its misbranding standards).

Mutual Pharm. Co., 459 F. Supp. 2d at 933.

Given that the FFDCA, unlike the Lanham Act, does not provide for a private right of action, courts have "tread[ed] carefully when applying the Lanham Act to the advertising of goods ... that are also subject to regulation by the [F]FDCA lest it be used as a vehicle to accomplish indirectly something a party could not accomplish directly." *Mutual Pharm. Co.*, 459 F. Supp. 2d at 934 (internal citations omitted). Thus, courts have dismissed Lanham Act claims that merely seek to enforce a violation of the FFDCA or FDA regulations, thereby attempting to circumvent the FFDCA's denial of a private right of action. *See Summit Tech, Inc. v. High-Line Med. Instruments, Co., et al.*, 922 F. Supp. 299, 306 (C.D. Cal. Feb. 28, 1996). Similarly, courts have found that they are unable to consider a Lanham Act claim seeking to "challenge determinations of the FDA." *See Rita Medical Sys., Inc. v. Resect Med., Inc.*, No. C 05-03291 WHA, 2006 WL 2038328, at *3 (N.D. Cal. July 17, 2006) (finding that court was unable to consider Lanham Act claim implicating review of FDA's determination that defendant was permitted to market device at issue because it was "substantially equivalent" to other devices on the market). Furthermore, reasoning that the proper interpretation and enforcement of relevant FDA regulations is not an issue properly decided as an original matter by a district court in a Lanham Act case, "courts have refused to permit a Lanham Act claim to proceed where, in order to determine the falsity or misleading nature of the representation at issue, the court would be required to

interpret and then apply [F]FDCA statutory or regulatory provisions." *Mutual Pharm. Co.*, 459 F. Supp. 2d at 934; *see Summit Tech, Inc.*, 933 F. Supp. at 933-35 (dismissing Lanham Act claims that would have required the court to "perform an original interpretation" of the FDA regulations, as "the FDA has not yet determined how it will interpret and enforce its own regulations."); *see also Sandoz Pharms Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231-32 (3d Cir. 1990) (affirming district court's finding that plaintiff could not proceed on Lanham Act claim, based on allegedly inaccurate labeling, that would require court to "interpret ... and enforce ... potentially ambiguous FDA regulations and, thus, "determine preemptively how a federal agency will interpret and enforce its own regulations").

Concern regarding interference with the FFDCA and FDA regulations, "however, should not be seen as an invitation to leave the field completely occupied by the [F]FDCA; the Lanham Act has its place even with respect to goods otherwise subject to regulation by the [F]FDCA." *Mutual Pharm. Co.*, 459 F. Supp. 2d at 934 (internal citations omitted); *see Ethex Corp. v. First Horizon Pharm. Corp.*, 228 F. Supp. 2d 1048, 1055 (2002) (internal citations omitted) (False statements, however, are actionable under the Lanham Act even if they involve FDA-regulated products. But the cases have cautioned that the courts should not usurp the FDA's authority to interpret and enforce its own regulations."); *Summit Tech, Inc. v. High-Line Med. Instruments, Co., et al.*, 933 F. Supp. 918, 933 (C.D. Cal. July 16, 1996) ("[F]alse statements are actionable under the Lanham Act, even if their truth may be generally within the purview of the FDA."). Therefore, courts have allowed a Lanham Act claim to proceed where the claim "does not require an interpretation or application

of FDA regulations." *Summit Tech, Inc.*, 933 F. Supp. at 933, 935 (internal citations omitted); *see Grove Fresh Distribs., Inc. v. Flavor Fresh Foods, Inc.*, 720 F. Supp. 714, 715-16 (N.D. Ill. Sept. 28, 1989) (allowing plaintiff to pursue Lanham Act claim based on defendant's alleged misrepresentation that its orange juice is "100% orange juice from concentrate," as plaintiff did not rest claim on FFDCA violations and could establish Lanham Act violation without referencing FDA regulations defining "orange juice from concentrate"). Thus, "so long as courts are not required to perform authoritative interpretation and direct application of FDA regulations, then the simple fact that a matter touches upon an area dealt with by the FDA is not a bar to proceeding with a claim under the Lanham Act." *Mutual Pharm. Co.*, 459 F. Supp. 2d at 935 (*Summit Tech, Inc.*, 933 F. Supp. at 933) (internal quotations omitted).

Here, Coca Cola's objections are partially meritorious, as Pom's Lanham Act claim may be construed to challenge FDA regulations and require interpretation of the FDA's regulations implementing the naming and labeling of multiple-juice beverages. Specifically, the Complaint alleges that "[b]y name alone, one would expect that the primary ingredients in Coca Cola's Pomegranate Blueberry Product are pomegranate and blueberry juice" and objects to the misleading nature of the Juice's labeling. (*See* Compl. ¶ 22.) The FFDCA and the FDA implementing regulations, however, involve a number of requirements for labeling a multiple-juice beverage. Section 343(f) of the FFDCA governs the prominence of information required by the FFDCA to appear on the label of a food product and Section 343(I) of the FFDCA specifies that "A food shall be deemed to be misbranded ... [u]nless its label bears (1) the common or usual name of the food, if any there be, and (2) ... if

the food purports to be a beverage containing ... fruit juice, a statement with appropriate prominence on the information panel of the total percentage of such fruit ... juice contained in the food ...." 21 U.S.C. § 343(f), (l). The FDA's implementing regulations specify that the "common or usual name" of a diluted multiple-juice beverage that identifies a juice on the label other than in the ingredient statement, which also contains another juice or other juices that are not on the label, must indicate that the juice identified on the label "is not the only juice present," e.g., by using the word "blend." *See* 21 C.F.R. § 102.33(c). Furthermore, if the juice identified on the label is not the predominant juice, then the "common or usual name" must indicate that the juice is present as "flavor or flavoring" or include the percentage of that juice contained in the beverage. *See* 21 C.F.R. § 102.33(d). In addition, representing that the juice "is used as a flavor" exempts the multiple-juice beverage from the requirement that if using more than one constituent juice name other than in the ingredient statement, the juice names must be used in descending order of prominence by volume. 21 C.F.R. § 102.33(b). As such, Pom's Lanham Act claim, with regard to the Juice's name and labeling, may be construed as impermissibly challenging the FDA's regulations regarding an acceptable "common or usual name" and appropriate labeling for a multiple-juice beverage. *See Rita Medical Sys., Inc.*, 2006 WL 2038328, at *3. Moreover, if Pom's Lanham Act claim were to focus on areas covered by the FFDCA and the FDA-implementing regulations, the Court would be required to interpret and apply FDA regulations as to the labeling of the Juice, which the FDA has not considered or approved. *Sandoz Pharms Corp.*, 902 F.2d 222, 231-32 (3d Cir. 1990); *Summit Tech, Inc.*, 933 F. Supp. at 933-35; *Mu-*

tual Pharm. Co., 459 F. Supp. 2d at 934. The Court is unable to perform such an interpretation and application of the FDA's regulations as applied to the Juice, because it would "usurp[ ] the FDA's discretionary role in the application and interpretation of its regulations." *See Summit Tech, Inc.*, 922 F. Supp. at 306 (internal citation omitted).

Nevertheless, the Court is largely unpersuaded by Coca Cola's argument, as Coca Cola's argument does not address the majority of Pom's Lanham Act claim. Pom's Lanham Act claim alleges that Coca Cola misrepresents, in the Juice's advertising and marketing in addition to its packaging, that the Juice's "primary ingredients ... are pomegranate and blueberry juice." (*See* Compl. ¶ 8.) In contending that Pom's Lanham Act claim is merely an impermissible attempt to challenge the FDA's juice-naming and labeling requirements, Coca Cola ignores the allegations in the Complaint that extend beyond the "packaging" and "name" of the Juice to its "advertising" and "marketing," including Minute Maid's website, a depiction of which is attached to the Complaint. (*See* Compl. ¶¶ 20-22, Ex. B.) Pom's entire Lanham Act claim is not barred simply because the Juice, as a multiple-juice beverage, is an FDA-regulated product. *See Mutual Pharm. Co.*, 459 F. Supp. 2d at 934 (internal citations omitted); *Ethex Corp.*, 228 F. Supp. 2d at 1055; *Summit Tech, Inc.*, 933 F. Supp. at 933. The targeted FDA juice-naming and labeling regulations, which Pom's Complaint does not argue Coca Cola violates, do not bar Pom from showing that Coca Cola has otherwise advertised and marketed its product in a misleading manner that leads consumers to believe that the primary ingredients are pomegranate and blueberry. (*See generally* Compl.) Because the Court, in contexts beyond the Juice's formal

name and labeling areas for which there are relevant FDA regulations, will not be required to interpret FDA regulations, Pom's Lanham Act claim can proceed to the extent it seeks to redress Coca Cola's marketing and advertising in such areas. *See Summit Tech, Inc.*, 933 F. Supp. at 933, 935 (internal citations omitted); *Grove Fresh Distribs., Inc.*, 720 F. Supp. at 715-16.

Accordingly, the Court GRANTS IN PART Coca Cola's Motion to Dismiss Pom's Lanham Act claim only to the extent it challenges the Juice's formal name and labeling in areas for which the FDA has promulgated regulations implementing the FFDCA.

B. *State Law Claims*

1. *Preemption*

Pursuant to the Supremacy Clause, "Congress has the power to preempt state law." *Crosby v. National Foreign Trade Council*, 530 U.S. 363, 372, 120 S. Ct. 2288, 147 L. Ed. 2d 352 (2000) (internal citations omitted). In determining whether a state law is preempted, the "ultimate touchstone" is congressional intent. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996); *see English v. Gen. Elec. Co.*, 496 U.S. 72, 78-79, 110 S. Ct. 2270, 110 L. Ed. 2d 65 (1990) ("Pre[]emption is fundamentally a question of congressional intent."). "As a result, any understanding of the scope of a pre[]emption statute must rest primarily on a fair understanding of congressional purpose." *Medtronic, Inc.*, 518 U.S. at 485-86 (internal citations and quotations omitted).

Supreme Court precedent establishes that state law is preempted in three circumstances. *English v. Gen. Elec. Co.*, 496 U.S. 72, 78, 110 S. Ct. 2270, 110 L. Ed. 2d 65 (1990). First, in express preemption, Con-

gress may expressly define the extent to which its enactments preempt state law. *Id.* (internal citations omitted). In the absence of an express preemption provision, federal law may implicitly preempt state law. *See Crosby*, 530 U.S. at 372; *Freightliner Corp., et al. v. Myrick, et al.*, 514 U.S. 208, 287, 115 S. Ct. 1446, 131 L. Ed. 2d 324 (1995). Specifically, in field preemption, state law is preempted if it regulates conduct in a field that Congress intended federal law to occupy exclusively, which may be inferred if the "scheme of federal regulation [is] so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it," or in a field "in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Id.* at 79 (internal citations omitted). The Supreme Court has emphasized that if Congress has legislated in "a field which the States have traditionally occupied," courts "must start with the assumption that the historic police powers of the States were not to be superseded unless that was the clear and manifest purpose of Congress." *Medtronic*, 518 U.S. at 484; *see English*, 496 U.S. at 79 (internal citations omitted). Finally, in conflict preemption, state law is preempted "to the extent that it actually conflicts with federal law," making compliance with both federal and state law impossible, or where it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *English*, 496 U.S. at 79 (internal citations omitted); *see Crosby*, 530 U.S. at 373 (internal citations omitted).

If Congress includes an express preemption provision in a statute, the inclusion of this provision "implies-i.e., supports a reasonable inference—that Congress did not intend to pre[]empt other matters" beyond the pro-

vision's reach. *Freightliner Corp.*, 514 U.S. at 288. An express preemption provision, however, does not "entirely foreclose[] any possibility of implied pre[]emption." *Id.*; *see Geier, et al. v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 869, 120 S. Ct. 1913, 146 L. Ed. 2d 914 (2000).

a. *The FFDCA's Express Preemption Provision*

Coca Cola contends that Pom's state law claims are expressly preempted under the FFDCA's express preemption provision, as they seek to impose different juice-labeling requirements than those imposed by the FFDCA. (*See* Def.'s Mot. 12-14.) In opposition, Pom argues that its state law claims are not expressly preempted because none of the requirements mentioned in the FFDCA's express preemption provision are implicated by Pom's state law claims (*See* Pl.'s Opp'n 15-16.)

Because the FFDCA contains an express preemption provision, passed as part of the Nutrition Labeling and Education Act of 1990 ("NLEA"), the Court must first focus on the "plain wording of the clause" to identify the "domain expressly preempted" by the language of the statute. *See Sprietsma v. Marine*, 537 U.S. 51, 62-63, 123 S. Ct. 518, 154 L. Ed. 2d 466 (2002); *Medtronic, Inc.*, 518 U.S. at 484; *In re Farm Raised Salmon Cases*, 175 P.3d 1170, 1085 (2008) (internal citations omitted); *see also* Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (1990). This express preemption provision, Section 403A of the FFDCA or 21 U.S.C. § 343-1, provides that "no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce ... any requirement for the labeling of food of the type required by" various

sections of the FFDCA, including section 343(f), 343(i)(1), and 343(i)(2), which may be relevant in this case, "that is not identical to the requirement of such section ...." 21 U.S.C. § 343-1(a)(2), (3); *In re Farm Raised Salmon Cases*, 175 P.3d at 1086 (internal citations omitted). For the purposes of this section, " 'not identical to' ... means that the State requirement directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food, or concerning a food container, that: (i) Are not imposed by or contained in the applicable provision (including any implementing regulation) ... or (ii) Differ from those specifically imposed by or contained in the applicable provision (including any implementing regulation) ...." 21 C.F.R. § 100.1(c)(4).

Under this statutory framework, state law that imposes obligations that are "not identical to" those imposed in Section 343(f) and 343(i) of the FFDCA, as well as the FDA's implementing regulation for these sections, are expressly preempted. *See* 21 U.S.C. § 343-1(a)(2), (3). As previously explained, Section 343(f) of the FFDCA governs the prominence of information required by the FFDCA to appear on the label of a food product and Section 343(i) of the FFDCA specifies that "A food shall be deemed to be misbranded ... [u]nless its label bears (1) the common or usual name of the food, if any there be, and (2) ... if the food purports to be a beverage containing ... fruit juice, a statement with appropriate prominence on the information panel of the total percentage of such fruit ... juice contained in the food ...." 21 U.S.C. § 343(f), (i). The FDA's implementing regulations specify that the "common or usual name" of a diluted multiple-juice beverage that identifies a juice on the label other than in the ingredient statement, which also contains another juice or other juices that

are not on the label, must indicate that the juice identified on the label "is not the only juice present," e.g., by using the word "blend." *See* 21 C.F.R. § 102.33(c). Furthermore, if the juice identified on the label is not the predominant juice, then the "common or usual name" must indicate that the juice is present as "flavor or flavoring" or include the percentage of that juice contained in the beverage. *See* 21 C.F.R. § 102.33(d). In addition, representing that the juice "is used as a flavor" exempts the multiple-juice beverage from the requirement that if using more than one constituent juice name other than in the ingredient statement, the juice names must be used in descending order of prominence by volume. 21 C.F.R. § 102.33(b). Given the allegations in the Complaint regarding Coca Cola's deceptive "packaging" of the Juice, which is a multiple-juice beverage containing apple juice, grape juice, pomegranate juice, and blueberry juice, it appears as though Pom, through its state law claims, may attempt to impose requirements differing from these naming and labeling requirements for multiple-juice beverages in the FFDCA and the FDA's implementing regulations. (*See* Compl. ¶¶ 8, 19, 20, 22.) Section 403A of the FFDCA or 21 U.S.C. § 343-1, however, explicitly prohibits such an attempt to impose varying obligations through state law.

Accordingly, the Court GRANTS IN PART Coca Cola's Motion to Dismiss, finding that Pom's state law claims for false advertising under California Business and Professions Code § 17500 and statutory unfair competition under California Business and Professions Code § 17200 are preempted to the extent they seek to

impose any obligations that are "not identical to"[2] the sections of the FFDCA, including the FDA's implementing regulations, referenced in Section 403A of the FFDCA or 21 U.S.C. § 343-1, the only relevant sections of which appear to be Section 343(f) and 343(i). *See* 21 U.S.C. §§ 343(f), (i); 343-1.

b. *Implied Preemption*

Coca Cola further argues that Pom's state law claims are impliedly preempted because the FFDCA is a comprehensive regulatory scheme of branding and labeling food products and the state law claims create obstacles to the accomplishment of Congress' objectives in enacting the legislation and conflict with the FDA's comprehensive beverage-naming regulations. (*See* Def.'s Mot. 14-15.) Pom, however, contends that its state claims are not impliedly preempted because the FFDCA's express preemption provision evidences that Congress intended to create a narrow preemptive field in light of historical state regulation of food and beverage labeling and false advertising. (*See* Pl.'s Opp'n 16-19.)

As an initial matter, the Court's implied preemption analysis is informed by Supreme Court precedent establishing that the presence of an express preemption provision, like that in the FFDCA, "implies—i.e., supports a reasonable inference—that Congress did not intend to pre[ ]empt other matters" beyond the reach of this provision. *See Freightliner Corp.*, 514 U.S. at 288; *see also Geier, et al.*, 529 U.S. at 869. Furthermore, consumer protection laws are within the states' historic police powers, which states have continually exercised

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[2] For FFDCA preemption purposes, "not identical to" has the meaning prescribed in 21 C.F.R. § 100.1(c)(4).

to protect the health and safety of their citizens. *See Medtronic, Inc.*, 518 U.S. at 475; *In re Farm Raised Salmon Cases*, 175 P.3d at 1088. Similarly, states' historic police powers also include laws protecting their people "against fraud and deception in the sale of food products at retail markets within their borders." *See Fla. Lime & Avocado Growers, Inc., et al. v. Paul, et al.*, 373 U.S. 132, 144, 83 S. Ct. 1210, 10 L. Ed. 2d 248 (1963) (internal citations omitted); *see also In re Farm Raised Salmon Cases*, 175 P.3d at 1088 (internal citations omitted) ("Laws regulating the proper marketing of food, including the prevention of deceptive sales practices, are likewise within states' historic police powers. Indeed, as early as the 1860's, California was enacting laws regulating food marketing."). Given that the state laws at issue regulate a field that states have traditionally occupied, the Court, in accordance with Supreme Court precedent, must work on the presumption that Congress did not intend to preempt state law, which can be overcome only if Congress' intention to preempt is "clear and manifest." *See Medtronic*, 518 U.S. at 484; *English*, 496 U.S. at 79.

Further suggesting a lack of congressional intent to implicitly preempt state law through the FFDCA, in the NLEA, which added the FFDCA's express preemption provision, Congress expressly stated that the "[NLEA] shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under section 403A of the [FFDCA]." Nutrition Labeling and Education Act of 1990; *see In re Farm Raised Salmon Cases*, 175 P.3d at 1085. This congressional statement is of particular importance in a preemption analysis where the "ultimate touchstone" is congressional intent. *See Medtronic*, 518 U.S. at 485; *English*, 496 U.S. at 78-79. As the Supreme Court of

California has explained, Congress, with this statement, "made clear that the preemptive scope of [the FFDCA's express preemption provision] was to sweep no further than the plain language of the statute itself." *In re Farm Raised Salmon Cases*, 175 P.3d at 1091. Furthermore, the statement "evidences an intent to allow state and federal regulation to co-exist." *Id.* Although the Court is aware that Congress and the FDA, through regulations implementing the FFDCA, have enacted a number of food-labeling requirements, given that an express preemption provision in itself supports "a reasonable inference" that Congress did not intend to preempt matters beyond the scope of this provision, that Congress explicitly stated in an amendment to the FFDCA its intention not to preempt state law other to the extent it is preempted in the FFDCA's express preeemption provision, and the assumption against preemption exercised in fields traditionally regulated by state police powers, the Court finds that Congress did not intend federal law to occupy exclusively the food-labeling and advertising field. Therefore, the Court will not extend preemption beyond the limits expressly identified by Congress in the FFDCA's express preemption provision and finds that Pom's state law claims are not impliedly preempted on "field preemption" grounds.

Finally, although Coca Cola vaguely contends that the state law claims "conflict with the FDA's comprehensive beverage-naming regulations," Coca Cola does not specify any implicated regulations beyond those already found to expressly preempt state law claims. (*See* Def.'s Mot. 14-15.) Furthermore, Coca Cola does not even attempt to argue that compliance with both the federal and state law at issue is impossible. (*See generally* Def.'s Mot. 14-15.) As such, the Court finds

that the state law claims are not impliedly preempted on "conflict preemption" grounds.

Accordingly, the Court DENIES IN PART Coca Cola's Motion to Dismiss to the extent it argues that Pom's state law claims are impliedly preempted.

2. *Safe Harbor Doctrine*

Coca Cola argues that California's safe harbor doctrine bars Pom's state law claims because "the [F]FDCA and the FDA regulations governing the name of multiple-juice beverages clearly permit a juice beverage to be named by non-primary ingredients where words such as 'flavored' and 'blend' are used." (Def.'s Mot. 15-16; *see* Reply Mem. P. & A. Supp. Notice Mot. & Mot. Dismiss Pursuant to Fed. R. Civ. P. 12(b)(6) ("Def.'s Reply") 5.) The safe harbor doctrine "simply holds that a plaintiff may not bring an action under [California Business and Professions Code § 17200 that] challeng[es] business practices specifically permitted by other statutes." *McKell, et al. v. Wash. Mut., Inc., et al.*, 142 Cal. App. 4th 1457, 1474, 49 Cal. Rptr. 3d 227 (Cal. Ct. App. Sept. 18, 2006). Specifically, the safe harbor doctrine provides that "[i]f the Legislature has permitted certain conduct or considered a situation and concluded no action should lie, courts may not override that determination." *Cel-Tech Commc'ns, Inc., et al. v. Los Angeles Cellular Tel. Co.*, 20 Cal. 4th 163, 83 Cal. Rptr. 2d 548, 973 P.2d 527, 541 (1999). For the safe harbor doctrine to apply, the legislation must "actually 'bar' the action or clearly permit the conduct." *Id.* In other words, "courts may not use the unfair competition law to condemn actions the Legislature permits. Conversely, the Legislature's mere failure to prohibit an activity does not prevent a court from finding it unfair." *Id.* at 542.

To the extent the safe harbor doctrine applied in this case, it would only bar Pom's claim for statutory unfair competition under California Business and Professions Code § 17200 with respect to "business practices specifically permitted" or conduct "clearly permit[ted]" by the FFDCA, namely those specifying permissible "common or usual" names for multiple-juice beverages. *See Cel-Tech Commc'ns, Inc., et al.*, 83 Cal. Rptr. 2d 548, 973 P.2d at 541; *McKell, et al.*, 142 Cal. App. 4th at 1474, 49 Cal. Rptr. 3d 227. Because Coca Cola merely contends that the safe harbor doctrine applies to the "FDA's juice naming regulations" and the Court has already held that Pom's state law claims are expressly preempted to the extent they seek to impose obligations differing from those contained in the FFDCA and its accompanying FDA regulations regarding the Juice's "common or usual name," the safe harbor would not extend beyond the portion of the claims that the Court has already found to be expressly preempted by the FFDCA. *See* Def.'s Mot. 16; *supra* Part II.B.1.a. Accordingly, the Court declines to determine the issue.

III. *RULING*

For the foregoing reasons, Coca Cola's Motion is GRANTED IN PART, DENIED IN PART.

IT IS SO ORDERED.

APPENDIX G

STATUTORY AND REGULATORY PROVISIONS

15 U.S.C. § 1125: False designations of origin, false descriptions, and dilution forbidden

(a) Civil action

(1) Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which—

(A) is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person, or

(B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities,

shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

* * *

(c) Dilution by blurring; dilution by tarnishment

* * *

(3) Exclusions

The following shall not be actionable as dilution by blurring or dilution by tarnishment under this subsection:

(A) Any fair use, including a nominative or descriptive fair use, or facilitation of such fair use, of a famous mark by another person other than as a designation of source for the person's own goods or services, including use in connection with—

(i) advertising or promotion that permits consumers to compare goods or services; or

(ii) identifying and parodying, criticizing, or commenting upon the famous mark owner or the goods or services of the famous mark owner.

(B) All forms of news reporting and news commentary.

(C) Any noncommercial use of a mark.

* * *

15 U.S.C. § 1127: Construction and definitions; intent of chapter

* * *

The intent of this chapter is to regulate commerce within the control of Congress by making actionable the deceptive and misleading use of marks in such commerce; to protect registered marks used in such commerce from interference by State, or territorial legislation; to protect persons engaged in such commerce against unfair competition; to prevent fraud and deception in such

commerce by the use of reproductions, copies, counterfeits, or colorable imitations of registered marks; and to provide rights and remedies stipulated by treaties and conventions respecting trademarks, trade names, and unfair competition entered into between the United States and foreign nations.

21 U.S.C. § 337: Proceedings in name of United States; provision as to subpoenas

(a) Except as provided in subsection (b) of this section, all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

* * *

21 U.S.C. § 343: Misbranded food

A food shall be deemed to be misbranded—

(a) False or misleading label

If

(1) its labeling is false or misleading in any particular, or

(2) in the case of a food to which section 350 of this title applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 350 (b)(2) of this title.

* * *

(f) Prominence of information on label

If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

* * *

(i) Label where no representation as to definition and standard of identity

Unless its label bears

(1) the common or usual name of the food, if any there be, and

(2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient and if the food purports to be a beverage containing vegetable or fruit juice, a statement with appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice contained in the food; except that spices, flavorings, and colors not required to be certified under section 379e (c) of this title [1] unless sold as spices, flavorings, or such colors, may be designated as spices, flavorings, and colorings without naming each. To the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

* * *

21 U.S.C. § 343-1: National uniform nutrition labeling

(a) Except as provided in subsection (b) of this section, no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—

(1) any requirement for a food which is the subject of a standard of identity established under section 341 of this title that is not identical to such standard of identity or that is not identical to the requirement of section 343(g) of this title, except that this paragraph does not apply to a standard of identity of a State or political subdivision of a State for maple syrup that is of the type required by sections 341 and 343(g) of this title,

(2) any requirement for the labeling of food of the type required by section 343(c), 343(e), 343(i)(2), 343(w), or 343(x) of this title that is not identical to the requirement of such section, except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 343(c) of this title and that is applicable to maple syrup,

(3) any requirement for the labeling of food of the type required by section 343(b), 343(d), 343(f), 343(h), 343(i)(1), or 343(k) of this title that is not identical to the requirement of such section, except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 343(h)(1) of this title and that is applicable to maple syrup,

(4) any requirement for nutrition labeling of food that is not identical to the requirement of section 343(q) of this title, except a requirement for nutri-

tion labeling of food which is exempt under subclause (i) or (ii) of section 343(q)(5)(A) of this title, or

(5) any requirement respecting any claim of the type described in section 343(r)(1) of this title, made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title, except arequirement respecting a claim made in the label or labeling of food which is exempt under section 343(r)(5)(B) of this title.

Paragraph (3) shall take effect in accordance with section 6(b) of the Nutrition Labeling and Education Act of 1990.

* * *

21 U.S.C. § 343-1 Note (Construction of Pub. L. No. 101-535)

Section 6(c) of Pub. L. 101-535 provided that:

(1) The Nutrition Labeling and Education Act of 1990 [Pub.L. 101-535, Nov. 8, 1990, 104 Stat. 2353, for distribution of which see Short Title note set out under section 301 of this title and Tables] shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under section 403A of the Federal Food, Drug, and Cosmetic Act [this section].

* * *

21 C.F.R. § 102.33: Beverages that contain fruit or vegetable juice

(a) For a carbonated or noncarbonated beverage that contains less than 100 percent and more than 0 percent fruit or vegetable juice, the common or usual name shall be a descriptive name that meets the requirements of § 102.5(a) and, if the common or usual name uses the word "juice," shall include a qualifying term such as "beverage," "cocktail," or "drink" appropriate to advise the consumer that the product is less than 100 percent juice (e.g., "diluted grape juice beverage" or "grape juice drink").

(b) If the product is a diluted multiple-juice beverage or blend of single-strength juices and names, other than in the ingredient statement, more than one juice, then the names of those juices, except in the ingredient statement, must be in descending order of predominance by volume unless the name specifically shows that the juice with the represented flavor is used as a flavor (e.g., raspberry-flavored apple and pear juice drink). In accordance with § 101.22(i)(1)(iii) of this chapter, the presence of added natural flavors is not required to be declared in the name of the beverage unless the declared juices alone do not characterize the product before the addition of the added flavors.

(c) If a diluted multiple-juice beverage or blend of single-strength juices contains a juice that is named or implied on the label or labeling other than in the ingredient statement (represented juice), and also contains a juice other than the named or implied juice (nonrepresented juice), then the common or usual name for the product shall indicate that the represented juice is not the only juice present (e.g., "Apple blend; apple juice in a blend of two other fruit juices.")

(d) In a diluted multiple-juice beverage or blend of single-strength juices where one or more, but not all, of the juices are named on the label other than in the ingredient statement, and where the named juice is not the predominant juice, the common or usual name for the product shall:

(1) Indicate that the named juice is present as a flavor or flavoring (e.g., "Raspcranberry"; raspberry and cranberry flavored juice drink); or

(2) Include the amount of the named juice, declared in a 5-percent range (e.g., Raspcranberry; raspberry and cranberry juice beverage, 10- to 15-percent cranberry juice and 3- to 8-percent raspberry juice). The 5-percent range, when used, shall be declared in the manner set forth in § 102.5(b)(2).

(e) The common or usual name of a juice that has been modified shall include a description of the exact nature of the modification (e.g., "acid-reduced cranberry juice," "deflavored, decolored grape juice").

(f) If the product is a beverage that contains a juice whose color, taste, or other organoleptic properties have been modified to the extent that the original juice is no longer recognizable at the time processing is complete, or if its nutrient profile has been diminished to a level below the normal nutrient range for the juice, then the source fruits or vegetables from which the modified juice was derived may not be depicted on the label by vignette or other pictorial representation.

(g)(1) If one or more juices in a juice beverage is made from concentrate, the name of the juice must include a term indicating that fact, such as "from concentrate," or "reconstituted." Such terms must be included in the name of each individual juice or it may be stated once

adjacent to the product name so that it applies to all the juices, (e.g., "cherry juice (from concentrate) in a blend of two other juices" or "cherry juice in a blend of 2 other juices (from concentrate)"). The term shall be in a type size no less than one-half the height of the letters in the name of the juice.

(2) If the juice is 100 percent single species juice consisting of juice directly expressed from a fruit or vegetable whose Brix level has been raised by the addition of juice concentrate from the same fruit or vegetable, the name of the juice need not include a statement that the juice is from concentrate. However, if water is added to this 100 percent juice mixture to adjust the Brix level, the product shall be labeled with the term "from concentrate" or "reconstituted."

OPPOSITION BRIEF

RECORD
AND
BRIEFS

No. 12-761

IN THE

Supreme Court of the United States

POM WONDERFUL LLC,

Petitioner,

—v.—

THE COCA-COLA COMPANY,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF IN OPPOSITION TO PETITION

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The Coca-Cola Company ("Coca-Cola") respectfully submits this response to the petition of Pom Wonderful LLC ("Pom") for a writ of certiorari to the United States Court of Appeals for the Ninth Circuit in this case.

QUESTION PRESENTED

Whether the Ninth Circuit correctly held that a private litigant cannot use the Lanham Act's general prohibition against "misleading" statements to challenge a product name and label specifically authorized, and deemed "not misleading," by regulations duly issued by the U.S. Food and Drug Administration pursuant to the Food, Drug and Cosmetic Act.

RULE 29.6 DISCLOSURE

The Coca-Cola Company certifies that it has no parent corporation and that no publicly held corporation owns 10% or more of its stock.

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INTRODUCTION

Pom's petition is built on an erroneous premise: that the Ninth Circuit held the Lanham Act inapplicable to any label regulated by the U.S. Food and Drug Administration ("FDA"). According to Pom, "the Ninth Circuit concluded that Pom's Lanham Act claim was barred simply because the FDA regulates Coca-Cola's label." Pet. at 18. Indeed, Pom asserts, the "court of appeals allowed the FDA's *mere authority to regulate* juice labeling to bar application of the Lanham Act to any label falling within that authority." *Id.* at 13 (emphasis in original).

That is simply not what the Ninth Circuit held, or even what the proceedings below were about. Rather, both the district court and the court of appeals reached the much narrower conclusion that product labeling that is *specifically authorized* by the Food, Drug and Cosmetic Act ("FDCA") and/or implementing regulations issued by the FDA cannot be challenged as "false or misleading" under the general proscriptions of the Lanham Act. In other words, once Congress and FDA consider and directly approve a label statement as accurate and non-misleading, a private party cannot contest that very statement, or attempt to show that it is or false or deceptive, under another federal statute.

This decision was manifestly correct and, indeed, was the only sensible ruling the court below could have made. No other federal court of appeals—and certainly no decision by this Court—has ever reached a different conclusion. Allowing litigants to assert the kinds of claims that Pom

advocates would not only undermine the regulatory scheme that Congress and FDA have put in place, but would squander the scarce governmental resources about which Pom professes to be concerned. Pom's petition should be denied, and the decision below permitted to stand.

STATEMENT OF THE CASE

Coca-Cola, through its Minute Maid® business unit, markets a "Pomegranate Blueberry Flavored Blend of 5 Juices"—a 100% juice product flavored with small amounts of pomegranate juice, blueberry juice, and other natural flavors that give the juice a pomegranate-blueberry taste.[1] Coca-Cola includes on the product label a prominent graphic or "vignette" that depicts all five fruits used in the blend (apples, grapes, pomegranates, blueberries and raspberries). By featuring this image and by calling the product a "Pomegranate Blueberry **Flavored** Blend of 5 Juices," Coca-Cola accurately tells consumers what the product is (a blend of identified fruit juices) and, most importantly, what it tastes like (pomegranate and blueberry).

Detailed FDA regulations that govern the naming and labeling of flavored juice blends expressly authorize Coca-Cola's name and label. Indeed, as part of the formal notice-and-comment rulemaking process that led to the adoption of the applicable rules, FDA specifically considered how manufacturers should label "blends or mixtures of several juices, with one or two juices present in only minor amounts giving them flavor." 58 Fed. Reg.

[1] Pom refers to the product by the incomplete shorthand "Pomegranate Blueberry."

2897 at 2919 (Jan. 6, 1993). FDA found with respect to such products that the terms "flavored" and "blend" (1) inform consumers that the named fruit juices provide the product's characterizing flavor, but (2) do not erroneously suggest that these juices predominate by volume. FDA thus determined that naming and labeling a flavored juice blend in precisely the manner that Coca-Cola did is appropriate and adequate "to ensure that the label" of such a product "is not misleading." *Id.*

Pom has never disputed that Coca-Cola's product name is *authorized* by FDA regulations, or that FDA has determined that labels such as Coca-Cola's are *not misleading*. Nevertheless, Pom sued Coca-Cola under the Lanham Act—a general statute that prohibits any "false or misleading description" of goods and allows "any person who believes that he or she is likely to be damaged" to sue. Both the district court and the Ninth Circuit refused to permit such a private assault on FDA's authority.

In granting Coca-Cola's motion for summary judgment, the district court conducted an exhaustive review of the FDA regulations that govern the naming and labeling of flavored juice blends, including the years-long rulemaking proceeding that led to the adoption of these rules. The court first recognized that FDA had, after careful deliberation, "concluded that manufacturers of multiple-juice beverages may identify their beverages with a non-primary, characteristic juice, as Coca-Cola does here." App. 62a.[2] The district court then

[2] "App." refers to the Appendix to Pom's petition.

determined that the "naming and labeling" of Coca-Cola's product "comply" with all of the "rules promulgated by the FDA . . . to protect the public from unsafe or mislabeled products." *Id.* (citing 21 C.F.R. §§ 102.33(c), (d)). In particular, the product's name—Pomegranate Blueberry Flavored Blend of 5 Juices—"adequately and appropriately identifies pomegranate and blueberry as merely characterizing flavors," and the words "flavored" and "blend" are displayed on the label with requisite prominence. *Id.* 64a, 67a (citing 21 U.S.C. § 343(f)). Thus, the court concluded, "FDA has directly spoken on the issues" and has "reached a determination as to what is permissible." *Id.* 62a. Because Pom's claim "impermissibly challeng[ed] the FDA's" rules for "labeling [] a multiple-juice beverage," *id.*, Pom was "precluded from pursuing its Lanham Act claim against the naming and labeling" of the product. *Id.* 65a.

The Ninth Circuit affirmed this ruling in all respects, concluding that the district court was "right to hold" that where, as here, FDA has specifically authorized the use of certain labeling statements, allowing a private litigant to challenge those statements under the Lanham Act would unacceptably "undermine the FDA's regulations and expert judgments." *Id.* 10a.[3] The Ninth

[3] The court of appeals vacated the district court's dismissal of Pom's state-law claims on standing grounds, and remanded the case for consideration whether those claims are expressly preempted by federal law and/or barred by the California safe harbor doctrine. On February 13, 2013, the district court granted Coca-Cola's renewed motion for summary judgment with respect to Pom's state-law claims and dismissed Pom's action, with prejudice, in its entirety. *See Pom Wonderful LLC v. The Coca-Cola Co.*, No. 08 Civ. 6237, at Dkt. No. 417 (filed Feb. 13, 2013).

Circuit conducted its own thorough analysis and concluded that "FDA regulations authorize the name Coca-Cola has chosen" for its pomegranate blueberry flavored juice blend. *Id.* 9a. In particular, the regulations specify that "(1) Coca-Cola may give its product a name that refers to juices that provide the characterizing flavor, and (2) those juices need not predominate by volume . . . ." *Id.* Therefore, "Pom's challenge to the name 'Pomegranate Blueberry Flavored Blend of 5 Juices' would create a conflict with FDA regulations and would require us to undermine the FDA's apparent determination that so naming the product is not misleading." *Id.*

With respect to Pom's contention regarding the relative type sizes in which the various components of Coca-Cola's product name are displayed, the Ninth Circuit noted that "the FDCA and its implementing regulations have identified" not only "the words and statements that must or may be included on labeling," but also "how prominently and conspicuously those words and statements must appear." *Id.* 10a (citing 21 U.S.C. § 343(f), (i); 21 C.F.R. § 102.33(c), (d)). The court continued:

> Congress and FDA have thus spoken to what content a label must bear, and the relative sizes in which the label must bear it, so as not to deceive. . . . FDA has not . . . required that all words in a juice blend's name appear on the label in the same size or that words hew to some other standard that Pom might have us impose. If the FDA thought such a regulation were necessary "to render [that information]

> likely to be read and understood by the ordinary individual," 21 U.S.C. § 343(f), it could have said so. . . . But . . . for a court to act when the FDA has not—despite regulating extensively in this area—would risk undercutting the FDA's expert judgments and authority.

Id. 10a-11a.

The Ninth Circuit concluded its opinion with an express admonition that it was *not* adopting the blanket rule that Pom asks this Court to review. The court cautioned that, in barring Pom's suit, "[w]e do not suggest that mere compliance with the FDCA or with FDA regulations will always (or will even generally) insulate a defendant from Lanham Act liability." *Id.* 12a. Rather, it was the FDA's "comprehensive regulation of [juice] labeling"—including the very matters raised by Pom's lawsuit—and the Agency's affirmative decision "not to impose the requirements urged by Pom" that led the court of appeals to affirm the judgment below. *Id.* In other words, Pom's Lanham Act challenge was barred not because Coca-Cola's label was merely subject to federal regulation, but because Congress and FDA had considered the issues and expressly "authorize[d]" Coca-Cola to label its product in the manner it did. *Id.* 9a.

REASONS FOR DENYING THE PETITION

I. THE NINTH CIRCUIT'S DECISION IS WELL-REASONED AND SUPPORTED BY PRIOR RULINGS BY OTHER COURTS

As the foregoing discussion demonstrates, Pom's repeated assertions that the decision below "precluded *all* Lanham Act claims touching on food and beverage labeling" (Pet. at 20 (emphasis in original)) are simply incorrect. No court, least of all the Ninth Circuit, has ever held the Lanham Act inapplicable to product labels simply because they are regulated in some fashion, or because FDA has the authority to regulate them. Rather, the court of appeals here had to grapple with a situation that has only arisen in a small number of cases: a private plaintiff attempts to use the general proscriptions of the Lanham Act to challenge a statement that FDA has specifically determined to be truthful and "not misleading." Though such cases are rare (because few litigants think to bring them), they are not unheard of, and they invariably fail.

For example, in *American Home Prods. v. Johnson & Johnson*, 672 F. Supp. 135 (S.D.N.Y. 1987), a drug maker alleged that its competitor's statements that its aspirin product was "SAFE" were false and misleading in light of the health risks that aspirin poses for certain populations. FDA, however, had already determined—based upon a careful review of the scientific literature—that aspirin could be marketed as "safe and effective," and had issued regulations to that effect. The court held that this determination by FDA precluded such a challenge, and that the manufac-

turer's "compliance with FDA" prescriptions was a "complete defense" to the competitor's Lanham Act claim. *Id.* at 144-45. *See also Cytyc Corp. v. Neuromedical Sys., Inc.*, 12 F. Supp. 2d 296, 301 (S.D.N.Y. 1998) (statements that FDA has approved are "non-actionable" under the Lanham Act since "they are neither false nor misleading" as a matter of law); *Rita Med. Sys. v. Resect Med., Inc.*, No. 05 Civ. 03291, 2006 U.S. Dist. LEXIS 52366, at *9 (N.D. Cal. July 17, 2006) ("FDA authorization casts doubt on the viability of plaintiff's Lanham Act claim"); *VP Racing Fuels, Inc. v. Gen. Petroleum Corp.*, 673 F. Supp. 2d 1073, 1084 (E.D. Cal. 2009) (Lanham Act cannot be used to "nullify the safe harbor" that exists under other federal laws); *Wyeth v. Sun Pharm. Indus., Ltd.*, No. 09 Civ. 11726, 2010 U.S. Dist. LEXIS 18180, at **11, 18 (E.D. Mich. Mar. 2, 2010) ("The FDA is a governmental agency, and its decisions" may be challenged administratively but not "under the Lanham Act").

The Ninth Circuit's decision in this case is in keeping with this long line of precedent, and it makes perfect sense. Both the FDCA and the Lanham Act prohibit false or misleading statements on food and beverage labels.[4] But of the two statutes, only the FDCA is a mandatory regulatory scheme that sets forth labeling rules that manufacturers are obliged to follow. FDA has pro-

[4] Section 403(a) of the FDCA, 21 U.S.C. § 343(a), states that a food is "misbranded" if, *inter alia*, its label is "false or misleading in any particular." Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), similarly prohibits any "false or misleading representation of fact . . . in commercial advertising or promotion . . . ."

mulgated highly-specific rules for hundreds of foods and beverages, from "beef stew" (must be 25% meat), *see* 9 C.F.R. § 319.304, to "peanut butter" (must be 90% peanuts), *see* 21 C.F.R. § 164.150. FDA has even directed manufacturers to make claims on their labels that are arguably false. For example, FDA rules specify that foods with fewer than five calories per serving should be labeled as "zero calories," *see* 21 C.F.R. § 101.60, and foods with less than 0.5 grams of trans fats per serving as "zero trans fats," *see* 21 C.F.R. § 101.9(c)(2)(ii). Manufacturers should not be exposed to lawsuits by competitors under the Lanham Act simply because they have adhered to these FDA prescriptions. The Ninth Circuit recognized as much when it ruled that Pom's attack on Coca-Cola's FDA-authorized label was barred.

II. THE NINTH CIRCUIT'S DECISION DOES NOT CONFLICT WITH THIS COURT'S PRECEDENTS

As noted above, this Court has never held that a Lanham Act claim will lie in circumstances where the statement in question has been directly authorized by a federal agency such as the FDA. Pom nonetheless argues that the Ninth Circuit's decision departs from this Court's precedents in two ways. Neither contention has merit.

A. THERE WAS NO NEED TO APPLY THE IRRECONCILABLE CONFLICT STANDARD

First, relying on its misreading of the decision below, Pom asserts that, by holding the Lanham Act inapplicable to food and beverage labeling, the Ninth Circuit violated this Court's precedents that require that two overlapping federal statutes both be given effect, and neither construed to displace the other, unless they are in "irreconcilable conflict." This Court has indeed held that a later-enacted statute will not be construed to silently repeal an earlier one unless the statutes cannot be reconciled. *See, e.g., Morton v. Mancari*, 417 U.S. 535 (1974); *Branch v. Smith*, 538 U.S. 254 (2003). But these decisions have nothing to do with the ruling in this case. As detailed above, the court of appeals did not hold that the Lanham Act is inapplicable to food labeling, let alone that the FDCA had repealed (or even partially repealed) the Lanham Act. Rather, the court below did precisely what is was supposed to do and reconciled the two statutes, holding that the FDA's specific determination, pursuant to the FDCA, that juice labels like Coca-Cola's are not misleading precludes a private party from advancing the opposite position in a private lawsuit under the Lanham Act. Put differently, the court ruled that a statement expressly approved by the FDCA is not "false or misleading" under the Lanham Act as a matter of law. *See Cytyc*, 12 F. Supp. 2d at 301.

That ruling is hardly controversial. It is a basic tenet of statutory construction that specific provisions trump general ones. *RedLAX Gateway Hotel, LLC v. Amalgamated Bank*, 132 S. Ct. 2065, 2071

(2012); *see VP Racing*, 673 F. Supp. 2d at 1084 (general prohibitions against false and misleading statements "are not capable of co-existence" with a "more specific" regulation on point). The FDCA and its implementing regulations are more specific than the Lanham Act and expressly authorize Coca-Cola's name and label. Indeed, FDA rules state explicitly that it is "not misleading" to name a "multiple-juice beverage" for the juice(s) that provide the product's characterizing flavor (*e.g.*, pomegranate and blueberry)—even if those juices are "present in only minor amounts." 58 Fed. Reg. 2897 at 2919. These highly-specific prescriptions of the FDCA must control over the Lanham Act's general prohibition against "misleading" statements.

This conclusion is buttressed by the fact that the pertinent provisions of the FDCA post-date the Lanham Act.[5] As this Court has held:

> The classic judicial task of reconciling many laws enacted over time, and getting them to make sense in combination, necessarily assumes that the implications of a statute may be altered by the implications of a later statute. This is particularly so where the scope of the earlier statute is broad but the subsequent statutes more specifically address the topic at hand. . . . [A] specific policy embodied in a later federal statute should control our construction of the [earlier]

[5] As explained in Section II.B. *infra*, the relevant provisions of the FDCA were enacted in 1990 as part of the Nutritional Labeling and Education Act. The Lanham Act was enacted in 1946, and last amended in 1988.

> statute, even though it has not been expressly amended.

Food and Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 143 (2000) (quotations and citations omitted). This teaching fully supports the court of appeals' conclusion that the general proscriptions of the Lanham Act cannot be used to challenge statements expressly authorized under the subsequently-enacted, more specific provisions of the FDCA and its implementing regulations.

B. *WYETH V. LEVINE* IS READILY DISTINGUISHABLE

Pom next argues that the Ninth Circuit's decision cannot be squared with this Court's ruling in *Wyeth v. Levine*, 555 U.S. 555 (2009). In *Wyeth*, the Court held that the use of an FDA-approved label on a prescription drug did not preclude a state-law action for personal injury based on a manufacturer's failure to warn of the drug's known risks. In other words, States are free to impose tort liability for failure to warn about the potential side effets of a prescription drug even though FDA does not require the absent warnings.

Wyeth, however, was a preemption case; the issue was whether the FDCA impliedly preempted States from adopting their own requirements for drug labeling. The Court rested its decision that State regulation could coexist with FDA rules on the fact that Congress had chosen in the FDCA *not* to expressly preempt State drug labeling laws. This led the Court to conclude that FDA's drug labeling rules were intended as a floor, not a ceiling on regulation. *Id.* at 574-75.

Here the exact opposite is true. The statutory provisions that authorize FDA to regulate food labeling were added to the FDCA in 1990 with the passage of the Nutrition Labeling and Education Act ("NLEA"). Congress's purpose in enacting this legislation was twofold: (1) to "make sense of the confusing array of nutrition labels that confront all consumers every time they enter the supermarket" by mandating certain label disclosures (*see* 136 Cong. Rec. H5836-01 (July 30, 1990) (statement of Rep. Waxman)); and (2) to fix the lack of uniformity in the regulation of food labels that had emerged across all 50 States (*see* 136 Cong. Rec. S16607-02 (Oct. 24, 1990) (statement of Sen. Hatch) ("[I]t is wrong to . . . burden the manufacturer with the fear of potentially 50 different lawsuits from 50 different State attorneys general")). To further the second goal, Congress expressly preempted States from regulating food labels:

> no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce . . . . any requirement for the labeling of food of the type required by . . . [among others, Sections 343(f), which deals with naming, and 343(i), which deals with labeling] . . . that is not identical to the requirement of such section. . .[6]

[6] 21 U.S.C. § 343-1(a). A State requirement is "not identical to" federal requirements—and thus preempted—if it imposes labeling obligations that are "not imposed by or contained in the applicable provision (including any implementing regulation)" or that "[d]iffer from those specifically imposed by or contained in the applicable provision (including any implementing regulation)." 21 C.F.R. § 100.1(c)(4).

Congress's decision to expressly supplant State laws—including those that imposed more "stringent" requirements than the NLEA did[7]—shows that the NLEA and its implementing regulations were not intended as a "floor" but rather as the exclusive body of regulation to which food and beverage labels would be subject. Pom's suggestion that *Wyeth* allows for additional regulation on top of the NLEA ignores this fundamental distinction between the food and drug labeling provisions of the FDCA and contradicts Congress's expressed intent.

Pom's assertion that allowing Lanham Act challenges to labels expressly approved by FDA would "complement[ ] FDA regulation" (Pet. at 18) also makes no sense. As both the district court and the court of appeals recognized in their opinions in this case, permitting Pom's claim to proceed would invite "private parties [to] undermin[e], through private litigation, FDA's considered judgments." App. 11a. Congress has determined "to entrust matters of juice beverage labeling to the FDA," and FDA has responded with "comprehensive regulation of that labeling." *Id.* 12a. "In the circumstances here, the appropriate forum for Pom's complaints is the FDA"—not a private lawsuit under the Lanham Act. *Id.* (internal quotations omitted).

[7] *See* 58 Fed. Reg. 2464.

III. THERE IS NO CONFLICT AMONG COURTS OF APPEALS TO BE RESOLVED

Relying once again upon its flawed reading of the opinion below, Pom argues that the Ninth Circuit's decision is in conflict with rulings by several other courts of appeal, which have held that false or misleading product labels are actionable under the Lanham Act even though they are regulated by FDA. But as noted above, the Ninth Circuit *did not* hold that FDA-regulated conduct is immune from attack. To the contrary, it stated explicitly that "mere compliance with the FDCA or with FDA regulations" will not "always (or [ ] even generally) insulate a defendant from Lanham Act liability." *Id.* The court's holding in this case was instead predicated on the fact that FDA's "comprehensive regulation" of the juice labeling at issue "authorize[d]" the product name and label that Coca-Cola chose. *Id.* 9a, 12a.

Properly read, the Ninth Circuit's ruling is entirely consistent with the various decisions from the Third, Eighth and Tenth Circuits that Pom cites. These courts have all held that, in some circumstances, Lanham Act challenges to statements concerning federally-regulated products will lie.[8]

[8] *See Sandoz Pharm. Corp.* v. *Richardson-Vicks, Inc.*, 902 F.2d 222 (3d Cir. 1990) (Lanham Act challenge to drug label barred because it would have required court to interpret and enforce the FDCA); *Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934 (8th Cir. 2005) (allowing Lanham Act challenge to claim that product was FDA-approved); *Cottrell, Ltd.* v. *Biotrol Intern., Inc.*, 191 F.3d 1248 (10th Cir. 1999) (Lanham Act challenge allowed despite fact that product in question was regulated by the Federal Insecticide, Fungicide, and Rodenticide Act).

So too did the Ninth Circuit in this case. In fact, other courts of appeal have implicitly, if not explicitly, recognized that false or misleading label statements concerning FDA-regulated products are open to Lanham Act attack. *See, e.g., Mead Johnson & Co. v. Abbott Labs.*, 201 F.3d 883 (7th Cir. 2000); *Johnson & Johnson v. Carter-Wallace, Inc.*, 631 F.2d 186, 188 (2d Cir. 1980). Coca-Cola has never argued otherwise, and the Ninth Circuit did not contradict this well-accepted principle in its ruling. The court below merely agreed with other courts that, once the FDA explicitly approves a statement as "not misleading" and authorizes its inclusion on a product label, a competitor cannot challenge the accuracy of that statement through a private lawsuit under the Lanham Act.

IV. THE DECISION BELOW HAS NO WORRISOME IMPLICATIONS

Pom suggests that, if the Ninth Circuit's decision is permitted to stand, there effectively will be no regulation of food and beverage labels, and manufacturers will be free to deceive consumers (and harm competitors) with impunity. There is no merit to this argument.

First, as the decision below makes clear, Pom's claim was barred precisely *because of* the detailed regulatory scheme that Congress and FDA have put in place. Pom cites a General Accounting Office report that indicates that FDA lacks the resources to pursue individual actions against each manufacturer that adopts a deceptive label. That is precisely why FDA took the time decades

ago to study the issue, hold public hearings, and promulgate comprehensive regulations that dictate how all juice products—including flavored juice blends—should be labeled and promoted. This is not a case in which FDA has failed to exercise its statutory authority, or has done so only in minimal fashion. Rather, FDA has "regulat[ed] extensively in this area," App. 11a, and has set down rules that all juice manufacturers must follow.

Second, allowing private litigants to challenge FDA's labeling determinations by suing their competitors under the Lanham Act would lead to more confusion, not less. FDA has brought its expertise to bear and has decided "what content a label must bear, and the relative sizes in which the label must bear it, so as not to deceive." *Id.* 10a. Permitting lay judges and juries—which "lack the FDA's expertise in guarding against deception in the context of juice beverage labeling" (*id.* 12a)—to second-guess and contradict FDA's determinations would leave manufacturers with no clear rules to follow. Food and beverage companies would be subject to the views of multiple decision makers across the country as to how a product must be labeled in order to avoid consumer confusion. This was precisely the state of affairs that led Congress in 1990 to pass the NLEA, direct the FDA to promulgate a single set of regulations, and preempt States from imposing any requirements for food labels not identical to FDA requirements.

Finally, as Pom well knows, it simply is not the case that the U.S. Government is incapable of policing juice manufacturers who (unlike Coca-Cola) violate federal standards and engage in

deceptive labeling and promotion. In 2010, FDA issued a stern warning letter to Pom detailing numerous instances in which Pom had made unapproved claims that its juice products could prevent or treat a host of serious illnesses, including heart disease and cancer.[9] And just weeks ago, the U.S. Federal Trade Commission determined that these unsubstantiated health claims by Pom had amounted to a massive fraud on the American public, and warranted the issuance of a restraining order of unprecedented scope against Pom and its owners, Stewart and Lynda Resnick.[10] The Government does not need allies like Pom to help it fight deception in the realm of juice labeling.

[9] http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm202785.htm (last accessed February 11, 2013).

[10] *See* Opinion (http://www.ftc.gov/os/adjpro/d9344/130116pomopinion.pdf); Final Order (http://www.ftc.gov/os/adjpro/d9344/130116pomorder.pdf).

CONCLUSION

For the foregoing reasons, the Court should deny Pom's petition for a writ of certiorari.

Respectfully submitted,

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February 22, 2013

REPLY BRIEF

RECORD
AND
BRIEFS

Supreme Court, U.S.
FILED
MAR - 7 2013
OFFICE OF THE CLERK

No. 12-761

IN THE

Supreme Court of the United States

POM WONDERFUL LLC,

Petitioner,

v.

THE COCA-COLA COMPANY,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

REPLY BRIEF FOR PETITIONER

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IN THE

Supreme Court of the United States

No. 12-

POM WONDERFUL LLC,

Petitioner,

v.

THE COCA-COLA COMPANY,

Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

REPLY BRIEF FOR PETITIONER

Coca-Cola's opposition rests on the assertion (at 1) that the Ninth Circuit rejected Pom's Lanham Act challenge because it concluded that the label of Coca-Cola's "Pomegranate Blueberry" juice product was "specifically authorized" by the Food, Drug and Cosmetic Act ("FDCA"). But that assertion ignores the key portions of the court's opinion making clear that it was the FDA's regulatory authority that the court found dispositive. The Ninth Circuit's holding that Pom's Lanham Act claim could not proceed because Coca-Cola's label is subject to regulation by the FDA conflicts with decisions of this Court prescribing when one federal law can displace another and with decisions of other circuits permitting Lanham Act challenges de-

spite agency regulation. The court's decision also will have significant consequences: In a significant portion of the country, false and misleading labeling will no longer be subject to challenge by private citizens under the Lanham Act, leaving labels to be policed only by the understaffed and underfunded FDA.

I. COCA-COLA MISCHARACTERIZES THE NINTH CIRCUIT'S DECISION

Coca-Cola's arguments in opposition to certiorari are premised almost entirely on its contention that the court of appeals concluded that its label was "specifically authorized" by the FDCA. Opp. 1, 4; *see also, e.g.*, *id.* at 6 ("expressly 'authorize[d]'"), 10 ("FDA's specific determination"; "expressly approved"), 12 ("expressly authorized"), 15 ("authorize[d]"), 16 ("explicitly approve[d]" by FDA). This contention is the basis for Coca-Cola's denial that the Ninth Circuit disregarded this Court's precedent on reconciling federal statutes and departed from decisions of its sister courts of appeals on the important question whether mere agency regulation forecloses Lanham Act challenges by private parties. *See* Opp. 9-10, 15. But Coca-Cola's reading of the decision below is demonstrably wrong.

The Ninth Circuit recognized that Coca-Cola's label has never been reviewed by the FDA, *see* Pet. App. 11a-12a, and the court avoided making any definitive pronouncement about whether the label is "specifically authorized" by the FDA's regulations. To the contrary, the court explained that it was "primarily guided" in its decision "not by Coca-Cola's apparent compliance with FDA regulations but by Congress's decision to entrust matters of juice beverage labeling to the FDA and by the FDA's comprehensive regulation of that labeling." *Id.* at 12a. Because the court's decision rested on the

FDA's "comprehensive regulation" of juice labeling, and not Coca-Cola's alleged "compliance with FDA regulations," the court *did not even mention* the district court cases assertedly supporting an FDA compliance defense that Coca-Cola claims the Ninth Circuit "agreed with," Opp. 7-8, 16.

Rather than finding Coca-Cola's label "specifically authorized" by the FDCA, the Ninth Circuit recognized that the FDA might at some point conclude that the label as a whole is misleading in violation of the FDCA, *see* 21 U.S.C. § 343(a)—particularly in its use of a significantly smaller font size for the words "Flavored Blend of 5 Juices" than for the words "Pomegranate Blueberry," *see* Pet. 7. For example, after reviewing the FDA's juice-labeling regulations, the court stated:

> In concluding that Pom's claim is barred, we do not hold that Coca-Cola's label is non-deceptive. ... If the FDA believes that [the relative font sizes used in the label] mislead[] consumers, it can act. But the FDA has apparently not taken a view on whether Coca-Cola's labeling misleads consumers ....

Pet. App. 11a-12a. In its discussion of Coca-Cola's use of a reduced font size for the words "Flavored Blend of 5 Juices," the court similarly stated (in language Coca-Cola omits from its block quote with an ellipse): "If the FDA believes that more should be done to prevent deception, or that Coca-Cola's label misleads consumers, it can act." *Id.* at 11a; *compare* Opp. 6.

The Ninth Circuit made clear that the most that could be said about the FDA's font-size regulation was that the agency had not "*required* that all words in a juice blend's name appear on the label in the same size ...." Pet. App. 10a (emphasis added). The failure by

the FDA to require all of the words in a juice's name to be in the same font is a far cry from an affirmative *authorization* of the significantly reduced font size Coca-Cola used. *See* Pet. 7. Even here, the court hedged. It noted merely that "*so far as we can tell*," the FDA had not required all words in a name to be in the same font size. Pet. App. 10a (emphasis added); *compare* Opp. 5 (omitting the phrase "so far as we can tell").

The Ninth Circuit was similarly noncommittal in its discussion of the name of Coca-Cola's "Pomegranate Blueberry" product. Coca-Cola contends (at 4-5) that the court concluded the name was affirmatively "authorized" by the FDA's regulations, but it fails to note that what the court actually said was, "*as best we can tell*, FDA regulations authorize the name Coca-Cola has chosen." Pet. App. 9a (emphasis added); *compare* Opp. 5.[1] Indeed, while the Ninth Circuit explained that under the FDA's regulations a product's name may reference non-predominant juices if they "provide the characterizing flavor," Pet. App. 9a, nowhere did the court point to any evidence that the trace amounts of pomegranate juice and blueberry juice (.3% and .2%, respectively) in Coca-Cola's product provide "characterizing flavor."

Thus, far from making a definitive pronouncement that Coca-Cola's label was "authorize[d]" by the FDA's regulations, the court of appeals expressly left any assessment of that kind to the agency: "[W]e must keep in mind that we lack the FDA's expertise .... In the

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[1] Similarly, whereas the court of appeals referenced "FDA's *apparent* decision not to impose the requirements urged by Pom," Coca-Cola refers to the FDA's "*affirmative* decision." *Compare* Pet. App. 12a *with* Opp. 6 (emphases added).

circumstances here, the appropriate forum for [Pom's] complaints is the [FDA]." Pet. App. 12a (internal quotation marks omitted; second and third alterations in original)). The court of appeals precluded application of the Lanham Act to a broad range of potentially misleading statements solely on the ground that they are subject to FDA regulation. *See Id.* at 8a ("[T]he Lanham Act may not be used as a vehicle to usurp, preempt, or undermine FDA authority."). As explained below, this holding conflicts with precedent of this Court and decisions of other courts of appeals.

II. The Ninth Circuit's Decision Conflicts With This Court's Precedents

Coca-Cola concedes that under this Court's precedents, "a later-enacted statute will not be construed to silently repeal an earlier one unless the statutes cannot be reconciled." Opp. 10; *see Branch* v. *Smith*, 538 U.S. 254, 273 (2003) (setting forth "irreconcilable conflict" standard); *Morton* v. *Mancari*, 417 U.S. 535, 551 (1974). And Coca-Cola does not dispute that the Ninth Circuit failed to apply that standard in this case. Coca-Cola argues instead (at 10) that the "irreconcilable conflict" standard is inapplicable here because the Ninth Circuit held merely "that the FDA's specific determination ... that juice labels like Coca-Cola's are not misleading precludes a private party from advancing the opposite position ... under the Lanham Act." But this argument fails for the reasons set forth above: Coca-Cola has misread the Ninth Circuit's decision. The Ninth Circuit did not conclude that Coca-Cola's label was "not misleading" under the FDA's regulations. It held instead that the FDA's mere regulatory authority displaced the Lanham Act. *See supra* pp. 2-5.

Only by disregarding this Court's irreconcilable conflict standard was the Ninth Circuit able to conclude that the FDA's supposed "comprehensive regulation of [juice beverage] labeling," Pet. App. 12a, was sufficient to override the plain text of the Lanham Act. Coca-Cola has cited no decision of this Court holding that mere agency regulatory authority is sufficient to displace an otherwise applicable federal statute. *Cf. Credit Suisse Sec. (USA) LLC* v. *Billing*, 551 U.S. 264, 275-276 (2007) (requiring more than mere authority). Because Coca-Cola's label is not, in fact, "specifically authorized" by the FDCA or the FDA's regulations, application of the Lanham Act poses no irreconcilable conflict. This is not a case of a private litigant second-guessing a determination by the FDA. Moreover, as Pom explained in its petition (at 13-16), the FDCA and the Lanham Act are "fully capable of coexisting" because a party (like Coca-Cola) can comply with both statutes. *See United States* v. *Batchelder*, 442 U.S. 114, 122 (1979). As this Court held in *Wyeth* v. *Levine*, 555 U.S. 555, 577-578 (2009), the FDCA merely sets a "floor" for regulation of labels on which other laws can build. This is precisely what the Lanham Act does in this context by prohibiting companies from marketing products that mislead consumers. *See* Pet. 15-16.

Coca-Cola contends that *Wyeth* is inapplicable because it "was a preemption case" and because in that case, Congress had chosen not to expressly preempt state drug-labeling laws. Opp. 12. But the conflict preemption standard at issue in *Wyeth* is functionally equivalent to the irreconcilable conflict standard applicable here. *See* Pet. 17-18. And here, Congress has chosen not to displace the federal Lanham Act. Coca-Cola points (at 13) to the express preemption provision in the Nutrition Labeling and Education Act, but that

provision only preempts *states* from regulating food labels in a manner that is not identical to the FDCA. *See* 21 U.S.C. § 343-1(a). It says nothing of *other federal statutes*, which is what is at issue in this case.

Coca-Cola cites instances in which the FDA has "directed manufacturers to make claims on their labels that are arguably false." Opp. 8-9. But this case does not involve direction of that sort. The provisions of the FDCA relevant here do *not*, as Coca-Cola suggests (at 11), contain "highly-specific prescriptions" governing juice labeling. For example, the FDA's regulations did not require Coca-Cola to place the words "Flavored Blend of 5 Juices" in significantly smaller font than the words "Pomegranate Blueberry" on its juice product made up almost entirely of apple and grape juices (99.4%, *see* Pet. App. 2a). To the contrary, the FDCA provides that words required to be on a label must be "prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual ...." 21 U.S.C. § 343(f). Nor was the misleading name Coca-Cola chose mandated by the FDCA or the FDA's regulations. *See* Pet. 14.

In lieu of trying to explain why it believes the FDCA and the Lanham Act are in "irreconcilable conflict," Coca-Cola resorts (at 10-12) to alternative tools of statutory construction that even the Ninth Circuit did not invoke. But those canons of construction come into play only if a court has determined that two statutes conflict, which is not the case here. The first canon—that specific provisions trump general ones—applies where "a general permission or prohibition is contradicted by a specific prohibition or permission" or where the specific provision would be rendered superfluous by

the general one. *See RedLAX Gateway Hotel, LLC* v. *Amalgamated Bank*, 132 S. Ct. 2065, 2071 (2012). The second—the rule that a later statute controls the construction of an earlier one—is a tool used to "harmonize[]" "conflicting statutory provisions." *United States* v. *Estate of Romanil*, 523 U.S. 517, 534 (1998). Thus, neither standard has any relevance here.

Because the Ninth Circuit failed to adhere to this Court's precedents governing the implied repeal of a federal statute as well as the decision in *Wyeth*, this Court should grant review.

III. The Ninth Circuit's Decision Creates A Conflict Among The Courts Of Appeals

Coca-Cola makes almost no effort to reconcile the Ninth Circuit's sweeping displacement of the Lanham Act with decisions of at least three courts of appeals permitting Lanham Act claims to proceed in the face of agency regulation. In *Sandoz Pharmaceuticals Corp.* v. *Richardson-Vicks, Inc.*, 902 F.2d 222, 227-229 (3d Cir. 1990), the Third Circuit made clear that statements about a drug's effectiveness can be challenged under the Lanham Act if they are literally false or misleading even though such statements are also regulated by the FDA and FTC. In *Alpharma, Inc.* v. *Pennfield Oil Co.*, 411 F.3d 934, 939-941 (8th Cir. 2005), the Eighth Circuit permitted a Lanham Act challenge to the defendant's allegedly false assertion that its product had been approved by the FDA. And in *Cottrell, Ltd.* v. *Biotrol International, Inc.*, 191 F.3d 1248, 1254-1257 (10th Cir. 1999), the Tenth Circuit concluded that a Lanham Act challenge to certain statements about a product subject to regulation by the EPA could proceed.

All of these cases thus rejected the proposition that mere agency regulatory authority over a field—even if purportedly comprehensive—can displace the Lanham Act. Instead, the cases held that Lanham Act claims are barred only where they constitute an impermissible attempt by a private party to enforce the FDCA (or equivalent statute) or where they would necessarily require interpretation of FDA regulations or decisions (or their equivalent). *See* Pet. 19-23. As the court in *Cottrell* explained, a Lanham Act claim is not subject to dismissal just because it "touches on issues" subject to agency regulation: Unless a regulatory statute "explicitly precludes Lanham Act coverage, we refuse to limit the scope of the Lanham Act absent circumstances that inherently require interpretation" of relevant agency regulations or approvals. 191 F.3d at 1256.

Notably, Coca-Cola does not deny that the Third, Eighth, and Tenth Circuits have all "held that false or misleading product labels are actionable under the Lanham Act even though they are regulated by FDA." Opp. 16. In fact, Coca-Cola adds two more circuits to the tally, arguing that decisions of the Seventh and Second Circuits have also "recognized that false or misleading label statements concerning FDA-regulated products are open to Lanham Act attack." *Id.* (citing *Mead Johnson & Co.* v. *Abbott Labs.*, 201 F.3d 883 (7th Cir. 2000), and *Johnson & Johnson* v. *Carter-Wallace, Inc.*, 631 F.2d 186, 188 (2d Cir. 1980)). Coca-Cola's only response is to argue that the Ninth Circuit "did not contradict this well-accepted principle in its ruling" and that Pom's contrary reading of the Ninth Circuit's opinion is "flawed." Opp. 15-16. But it is Coca-Cola that has misread the Ninth Circuit's decision. As explained above, the Ninth Circuit held that Pom's Lanham Act claim could not proceed in light of the FDA's mere reg-

ulatory authority over juice labeling. *See supra* pp. 2-5. That holding cannot be reconciled with the decisions in *Alpharma*, *Sandoz*, and *Cottrell*. Indeed, Coca-Cola does not contest that *if* the Ninth Circuit's decision is taken at face value to preclude Lanham Act challenges to labels that are subject to "FDA's comprehensive regulation," Pet. App. 12a, then it conflicts with those decisions.

IV. The Question Presented Is Important

This case presents an important question regarding the interaction of the Lanham Act and federal agency regulatory regimes. *See* Pet. 24-28. Coca-Cola does not dispute that "FDA lacks the resources to pursue individual actions against each manufacturer that adopts a deceptive label." Opp. 16. It argues instead (at 17) that the FDA has "regulat[ed] extensively in this area" by promulgating rules governing juice labeling. But merely enacting rules, without the ability to enforce them, is insufficient to ensure that food products are not misleadingly labeled.

Coca-Cola also argues (at 17) that permitting Lanham Act suits challenging food labeling would lead to "confusion." But Coca-Cola does not explain why that would be the case. Companies face the possibility of Lanham Act challenges all the time. Every advertisement they run and every piece of promotional material they publish is subject to a Lanham Act challenge. One way to mitigate potential Lanham Act liability is to refrain from using product labels that your own employees have flagged as raising "a risk from a misleading standpoint." App. 35a. The FDCA expressly preempts *state* law in certain respects, *see* 21 U.S.C. § 343-1, but no provision of the Act indicates any intent by Congress to displace *federal* laws applicable to food labeling.

Coca-Cola does not dispute that the impact of the Ninth Circuit's opinion will extend beyond federal Lanham Act challenges involving juice labels. *See* Pet. 27-28. Indeed, recent events have only highlighted the need to clarify the standard for preclusion of food-labeling claims. On February 13, 2013, the district court in this case relied in part on the Ninth Circuit's analysis in finding Pom's *state-law* claims preempted. *See Pom Wonderful LLC* v. *Coca Cola Co.*, No. 2:08-cv-06237, 2013 WL 543361, at *4 n.1 (C.D. Cal. Feb. 13, 2013). Other district courts have likewise applied the decision to state-law claims. *See, e.g.*, *Ivie* v. *Kraft Foods Global Inc.*, No. 12-cv-2554, 2013 WL 685372, at *6-7 (N.D. Cal. Feb. 25, 2013).

Finally, the Court could consider holding the petition in this case pending resolution of *Mutual Pharmaceutical Co.* v. *Bartlett*, No. 12-142, which is set for argument on March 19, 2013. *Bartlett* addresses whether the FDCA preempts state-law design-defect claims against generic drugs where it would be impossible for the generic-drug manufacturer to comply with state law by altering the labeling of the drug required by the FDA or the FDA-approved design of the drug. The decision in *Bartlett* may inform the proper resolution of this case, where it was not impossible for Coca-Cola to comply with both the Lanham Act and the FDCA, and where the FDA did not review and approve, much less require, Coca-Cola's label.

CONCLUSION

For the foregoing reasons, Pom's petition for a writ of certiorari should be granted.

Respectfully submitted.

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MARCH 2013

AMICUS CURIAE BRIEF

RECORD
AND
BRIEFS

Supreme Court, U.S.
FILED
NOV 27 2013
OFFICE OF THE CLERK

No. 12-761

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v.

THE COCA-COLA COMPANY

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTION PRESENTED

Whether and to what extent the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*, and regulations promulgated under that Act preclude a food manufacturer from challenging the label of its competitor's product under Lanham Act § 43(a), 15 U.S.C. 1125(a), which provides a cause of action against anyone who, *inter alia*, "uses in commerce any word, term, name, symbol, or device, or any combination thereof * * * which * * * misrepresents the nature, characteristics, [or] qualities * * * of his * * * goods." 15 U.S.C. 1125(a)(1) and (B).

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In the Supreme Court of the United States

No. 12-761

POM WONDERFUL LLC, PETITIONER

v.

THE COCA-COLA COMPANY

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

This brief is submitted in response to the Court's order inviting the Solicitor General to express the views of the United States. In the view of the United States, the petition for a writ of certiorari should be denied.

STATEMENT

1. a. "Congress has regulated food and beverage labeling for more than 100 years." *Holk* v. *Snapple Beverage Corp.*, 575 F.3d 329, 331 (3d Cir. 2009). It did so first in the Federal Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768, then in the Federal Food, Drug, and Cosmetic Act (FDCA), ch. 675, 52 Stat. 1040, 21 U.S.C. 301 *et seq.*, and later through amendments to the FDCA. Congress amended the FDCA in 1990 to address nutrition labeling for nearly all food products for human consumption, including juices. Nutrition Labeling and Education Act of 1990 (NLEA), Pub. L. No. 101-535, 104 Stat. 2353. Throughout those efforts, "[m]isbranding was one of the

chief evils Congress sought to stop." *62 Cases of Jam* v. *United States*, 340 U.S. 593, 596 (1951).

The FDCA bans the introduction into or receipt in commerce of "misbranded" foods. 21 U.S.C. 331(a) and (c). "Food" includes any "article[] used for food or drink for man." 21 U.S.C. 321(f). Of relevance here, a food is misbranded if "its labeling is false or misleading in any particular," if required information is not sufficiently prominent and conspicuous on the label or labeling, or if its label fails to bear "the common or usual name of the food, if any there be, and * * * in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient." 21 U.S.C. 343(a), (f) and (i).[1]

To implement those provisions and provisions of the NLEA, and to "promote honesty and fair dealing in the interest of consumers," 21 U.S.C. 341, the Food and Drug Administration (FDA) has regulated many aspects of the naming and labeling of juice beverages. See 58 Fed. Reg. 2897-2926 (Jan. 6, 1993) (removing and promulgating scattered Sections of 21 C.F.R. Pts. 101, 102). Particularly relevant here are three provisions of 21 C.F.R. 102.33 addressing aspects of the naming and labeling of multi-juice beverages:

- Under Section 102.33(b), juices identified by name on the label (and not just listed in the ingredient statement)—"named juices" for short—"must be [named] in descending order of predominance by

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[1] The Federal Trade Commission (FTC) shares with the Food and Drug Administration enforcement authority over deceptive food labeling, advertising, and promotion. See 15 U.S.C. 45(a)(2), 52(a); 36 Fed. Reg. 18,539 (Sept. 16, 1971) (memorandum of understanding). The parties do not contend that the FTC's authority bears on the viability of petitioner's claim.

volume unless the name specifically shows that [a nonpredominant] juice [supplying a] represented flavor is used as a flavor (e.g., raspberry-flavored apple and pear juice drink)."

- Under Section 102.33(c), if a named juice is not the only juice present, "then the common or usual name for the product shall indicate that the [named] juice is not the only juice present (e.g., 'Apple blend; apple juice in a blend of two other fruit juices.')."
- Under Section 102.33(d), if a named juice is neither the only juice present nor the predominant juice, then the "common or usual name for the product shall" either "[i]ndicate that the named juice is present as a flavor or flavoring (e.g., 'Raspcranberry'; raspberry and cranberry flavored juice drink)" or "[i]nclude the amount of the named juice, declared in a 5-percent range."

The foregoing requirements under the FDCA as amended by the NLEA are not, as such, privately enforceable. See 21 U.S.C. 337(a) ("[A]ll such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States."); cf. *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001) ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance."). In addition, the NLEA prohibits any State from "directly or indirectly" establishing any requirement "that is not identical" to certain food-labeling requirements under the FDCA. 21 U.S.C. 343-1(a). But the NLEA does not expressly address its relationship to other federal laws.

b. The Trademark (Lanham) Act of 1946, ch. 540, 60 Stat. 427, amended existing trademark law to make "actionable the deceptive and misleading use of marks" in interstate commerce, to "protect persons engaged in such commerce against unfair competition," and to "provide rights and remedies stipulated by treaties and conventions respecting trademarks, trade names, and unfair competition entered into between the United States and foreign nations." 15 U.S.C. 1127. As amended, Section 43(a) of the Lanham Act creates a private civil action against

> [a]ny person who, on or in connection with * * * any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof * * * which * * * misrepresents the nature, characteristics, [or] qualities * * * of his * * * goods.

15 U.S.C. 1125(a)(1) and (B). Such an action may be brought "by any person who believes that he or she is or is likely to be damaged by such act." 15 U.S.C. 1125(a)(1).

2. Petitioner "produces, markets and sells bottled pomegranate juice and pomegranate juice blends, including a pomegranate blueberry juice blend." Pet. App. 1a. Respondent, doing business "under the brand Minute Maid, is one of [petitioner's] primary competitors in the bottled pomegranate juice market." *Id.* at 84a. In September 2007, respondent announced a new product called "Pomegranate Blueberry" or "Pomegranate Blueberry Flavored Blend of 5 Juices," consisting of "99.4% apple and grape juices, 0.3% pomegranate juice, 0.2% blueberry juice, and 0.1% raspberry juice." *Id.* at 1a-2a. The product's front label displays a graphic vignette depicting grapes, blueberries, and raspberries in front of

a halved pomegranate and a halved apple. Below the graphic vignette appear the words "Pomegranate Blueberry," and below those, in smaller type, the words "Flavored Blend of 5 Juices." See *id.* at 2a (reproducing label).

3. In September 2008, petitioner sued respondent under Section 43(a) of the Lanham Act.[2] Pet. App. 3a. Petitioner challenged the name, label, marketing, and advertising of respondent's juice, alleging that respondent misled consumers to believe that respondent's juice consists predominantly of pomegranate and blueberry juices when it in fact consists predominantly of less expensive apple and grape juices, thereby injuring both consumers and petitioner. *Id.* at 84a-85a. Petitioner described respondent's juice's label as containing "many misleading elements not required by federal or state regulation." First Am. Compl. ¶ 20. Petitioner alleged injury to its "business, reputation, and goodwill," and it sought damages, recovery of respondent's profits, and an injunction barring further false advertising of respondent's juice. *Id.* ¶¶ 33-35, Prayer for Relief.

The district court granted partial summary judgment to respondent on the Lanham Act challenge to the text displayed on the juice's label. Pet. App. 21a-73a. The court believed that "FDA has directly spoken on the issues that form the basis of" petitioner's claim in 21 C.F.R. 102.33(c) and (d). Pet. App. 62a. It further noted that 21 U.S.C. 343(f) requires only that respondent "prominently place the label on the Juice's bottle," which

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[2] Petitioner also brought claims under various California laws. Those claims are not at issue in this Court. See Pet. i. The district court granted summary judgment to respondent on those claims, No. 08-cv-6237, 2013 WL 543361 (C.D. Cal. Feb. 13, 2013), and petitioner's appeal is pending, No. 13-55770 (9th Cir.).

respondent "does sufficiently." Pet. App. 63a-64a. The court concluded that petitioner's claim failed because the common name for respondent's juice—"Pomegranate Blueberry Flavored Blend of 5 Juices"—"is expressly permitted (required here) by the FDA." *Id.* at 65a. Although the court found triable issues of fact on petitioner's advertising and marketing claims, *id.* at 72a, petitioner later stipulated that it could not carry its burden of proof on those claims in light of the court's order, and the court accordingly entered final judgment for respondent on all claims. *Id.* at 17a-19a. Accordingly, subsequent proceedings on petitioner's Lanham Act claim have been limited to material on the juice's label.

4. The court of appeals affirmed the district court's grant of summary judgment to respondent on petitioner's label-based Lanham Act claim. Pet. App. 1a-14a. It began by describing the FDCA as "comprehensively regulat[ing] food and beverage labeling." *Id.* at 6a. Next, acknowledging that "the Lanham Act and the FDCA can conflict with each other" but should each be given "as much effect * * * as possible," the court identified several scenarios in which, in its view, "the FDCA limits claims under the Lanham Act." *Id.* at 6a-7a (internal quotation marks and citation omitted). "A plaintiff may not, for example, sue under the Lanham Act to enforce the FDCA or its regulations," or "maintain a Lanham Act claim that would require a court originally to interpret ambiguous FDA regulations," or pursue a Lanham Act "claim [that] would require litigating whether [certain] conduct violates the FDCA." *Id.* at 7a (citing cases illustrating those principles). On the whole, the court concluded that generally, "the Lanham Act may not be used as a vehicle to usurp, preempt, or undermine FDA authority," but a court must still "focus

on the circumstances before it to strike a balance that disrupts the two statutory schemes as little as it can." *Id.* at 8a.

Applying those principles, the court of appeals concluded that "the FDCA and its regulations bar pursuit of both the name and labeling aspects of [petitioner's] Lanham Act claim." Pet. App. 9a. With respect to the juice's common name, the court explained that, because 21 C.F.R. 102.33(d) permits a manufacturer to name a beverage using the name of a flavoring juice that is not predominant, "as best we can tell, FDA regulations authorize the name [respondent] has chosen." Pet. App. 9a. Thus, the court reasoned, petitioner's challenge to the common name "'Pomegranate Blueberry Flavored Blend of 5 Juices' would create a conflict with FDA regulations and would require [the court] to undermine the FDA's apparent determination that so naming the product is not misleading." *Ibid.*

The court of appeals likewise concluded that petitioner's Lanham Act claim was precluded with respect to the label's presentation of the words "Pomegranate Blueberry" in "larger, more conspicuous type" than the words "Flavored Blend of 5 Juices" appearing below them. Pet. App. 10a. The court found that the FDCA and its implementing regulations "have specified how prominently and conspicuously those words and statements must appear." *Ibid.* (citing 21 U.S.C. 343(f) and (i); 21 C.F.R. 102.33(c) and (d)). "Congress and the FDA have thus considered and spoken to what content a label must bear, and the relative sizes in which the label must bear it, so as not to deceive," but "ha[ve] not (so far as we can tell) required that all words in a juice blend's name appear on the label in the same size." *Ibid.* The court observed that "[i]f the FDA believes more should be

done to prevent deception, or that [respondent's] label misleads consumers, it can act." *Id.* at 11a.

The court of appeals emphasized that it was not "hold[ing] that [respondent's] label is non-deceptive," or that "mere compliance with the FDCA or with FDA regulations will always (or will even generally) insulate a defendant from Lanham Act liability." Pet. App. 11a-12a. Rather, the court stated that it was guided by what it understood to be "Congress's decision to entrust matters of juice beverage labeling to the FDA and by the FDA's comprehensive regulation of that labeling." *Id.* at 12a. "In the circumstances here," the court concluded, "'the appropriate forum for [petitioner's] complaints is the [FDA].'" *Ibid.* (quoting *PhotoMedex, Inc.* v. *Irwin*, 601 F.3d 919, 929 (9th Cir. 2010)) (second set of brackets in original).

DISCUSSION

This case concerns the interplay of two federal statutes that apply to the label of a food product in commerce. The court of appeals correctly recognized that its task was to give maximum effect to each while respecting the other. Applying that principle, the court's rejection of petitioner's challenge under Section 43(a) of the Lanham Act to the common name of respondent's juice was sound, because that claim sought to impose liability for what FDA's regulations under the FDCA had specifically permitted. But the court of appeals should have permitted petitioner's Lanham Act challenge to proceed insofar as it concerns features of the juice's label that are not specifically addressed by the FDCA or FDA's regulations. The court concluded otherwise based on its observation that FDA had not (but could have) regulated the aspects of the label about which petitioner com-

plained. That reasoning endowed the FDCA's food-labeling provisions with too broad a preclusive reach.

Notwithstanding the court of appeals' error, further review is not warranted in this case. Because the court misinterpreted the preclusive reach of FDCA provisions that apply to food, the decision below does not conflict with the decisions petitioner identifies from this Court and other courts of appeals, each of which is distinguishable because (among other things) each concerned the preclusive effect of provisions of the FDCA that apply to a product other than food (or provisions of a statute other than the FDCA). Moreover, some doubt exists as to whether the summary-judgment record here properly presents the product-name/product-label dichotomy necessary for a sound treatment of the question presented.

A. The Court Of Appeals Erred By Giving The Federal Food, Drug, And Cosmetic Act Too Expansive A Preclusive Effect Over Claims Under Section 43(a) Of The Lanham Act

"[W]hen two statutes are capable of coexistence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective." *J. E. M. Ag Supply, Inc.* v. *Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 143-144 (2001) (citation omitted). Here, although Section 43(a) of the Lanham Act and the FDCA overlap in that each applies to the label of respondent's juice, each can be given effect, except where the Lanham Act would undo what Congress or FDA specifically required or permitted under the FDCA.

1. The court of appeals reasoned that, because FDA regulations appear to authorize the common name of respondent's juice, and because the FDCA and FDA's regulations generally address "what content a label must bear, and the relative sizes in which the label must bear

it, so as not to deceive," entertaining petitioner's Lanham Act challenge to the label on respondent's juice "would risk undercutting the FDA's expert judgments and authority." Pet. App. 9a-11a. In short, the court's decision rested on what it perceived as "Congress's decision to entrust matters of juice beverage labeling to the FDA and * * * the FDA's comprehensive regulation of that labeling." *Id.* at 12a.

That reasoning is too broad. In holding that Congress intended FDA to regulate juice labeling under the FDCA to the exclusion of the remedy under Section 43(a) of the Lanham Act, the court of appeals' analysis parallels that used in "so-called field pre-emption" cases, where "'the scope of a [federal] statute indicates that Congress intended federal law to occupy a field exclusively.'" *Kurns* v. *Railroad Friction Prods. Corp.*, 132 S. Ct. 1261, 1266 (2012) (brackets in original) (quoting *Freightliner Corp.* v. *Myrick*, 514 U.S. 280, 287 (1995)). Although federal-state preemption principles do not control the inquiry into whether "two [federal] statutes are capable of co-existence," *J. E. M. Ag Supply*, 534 U.S. at 143 (citation omitted), those principles may nonetheless be useful guides because they are calculated to identify laws that cannot co-exist. See Pet. 17-18. Moreover, circumstances that would not themselves support a finding of FDCA preemption of *state* remedies are unlikely to be a sufficient indication of Congress's intent to preclude an existing *federal* remedy. Here, a number of considerations, some borrowed by analogy from the preemption context, show that the FDCA does not occupy the juice-labeling field.

First, the court of appeals relied heavily on the existence of FDA regulations and the agency's ability to regulate further if it saw fit. But in the preemption

context, this Court has cautioned that "the mere existence of a federal regulatory or enforcement scheme," even a particularly detailed one, "does not by itself imply pre-emption of state remedies." *English* v. *General Elec. Co.*, 496 U.S. 72, 87 (1990). To hold otherwise would be "tantamount to saying that whenever a federal agency decides to step into a field, its regulations will be exclusive." *Hillsborough Cnty.* v. *Automated Med. Labs., Inc.*, 471 U.S. 707, 717 (1985). Likewise here, the court below was too quick to regard the commitment of authority to FDA as exclusive.

Second, the NLEA specifically disclaims federal occupation of the food-labeling field "unless such provision is expressly preempted" by 21 U.S.C. 343-1(a), which in turn forbids States from "directly or indirectly" establishing any requirement "that is not identical" to certain requirements under the FDCA. 21 U.S.C. 343-1(a) & note. That arrangement thus permits some state law unfair competition claims and bars others. By contrast, the court of appeals held that FDA's food-misbranding authority under the FDCA occupies the relevant field here to the total exclusion of the federal unfair-competition claim under Section 43(a) of the Lanham Act. It is counterintuitive to conclude that Congress intended a total displacement of a federal remedy but only a partial displacement of state remedies of a similar nature. And here in particular, it is implausible to think Congress meant to *favor* state remedies over a federal remedy, given that the NLEA was designed to promote "[n]ational[ly] uniform nutrition labeling," 21 U.S.C. 343-1.

Third, nothing in the FDCA, the NLEA, FDA's regulations, or the preambles to those regulations suggests that FDA has marked the metes and bounds of all possi-

ble misleading material on juice labels, or that its authority must be deemed exclusive even as to matters the agency has never specifically addressed. To the contrary, the preamble to the final juice-labeling rule makes clear that even when a manufacturer complies with 21 C.F.R. 102.33, there remains considerable potential for particular labels to prove misleading.[3] And as to unexercised regulatory authority, although the court of appeals professed to limit its holding to "matters of juice beverage labeling," Pet. App. 12a, its deference to FDA's available but unexercised authority would arguably preclude a Lanham Act challenge to the label of *any* food. Such reasoning could reach even the many foods that FDA's regulations do not specifically address at all. See generally 21 C.F.R. Subchap. B (regulating certain aspects of the labeling of food for human consumption, and defining common names of certain standardized foods).

Fourth, petitioner's use of the Lanham Act to challenge a food label is not novel. Congress first provided a private right of action in the Lanham Act eight years

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[3] For example, although 21 C.F.R. 102.33(b) permits the primary declaration of a characterizing juice even if "it is not the most predominant juice," FDA cautioned that "there is great potential for [such a] label to misrepresent the contribution of the named juice to the product" and that "this provision does not relieve the manufacturer of the obligation to label the product in a truthful and nonmisleading manner." 58 Fed. Reg. 2920 (Jan. 6, 1993). Likewise, the use of vignettes on an otherwise-appropriate label can raise misbranding concerns. See *id.* at 2922 ("[F]or a beverage label to not be misleading, it is necessary that the vignette and other label statements on the beverage not conflict in any way."); *ibid.* ("[FDA] will determine on a case-by-case basis whether a vignette is misleading because it is not consistent with other label information or for other reasons.").

after giving FDA authority in the FDCA to regulate the misbranding of food products. See 21 U.S.C. 331-334, 343, 371 (Supp. IV 1938); 15 U.S.C. 1125 (1946). Congress has repeatedly amended both laws without addressing their overlap. In that time, food labels have been challenged under Section 43(a) of the Lanham Act. *E.g.*, *Hesmer Foods, Inc.* v. *Campbell Soup Co.*, 346 F.2d 356, 359 (7th Cir.) (naming a product "Barbecue Beans" despite the fact it neither contains meat nor was cooked over an open fire), cert. denied, 382 U.S. 839 (1965); *Potato Chip Inst.* v. *General Mills, Inc.*, 333 F. Supp. 173 (D. Neb. 1971) (addressing challenge to package label describing dehydrated potato product "CHIPOS" as potato chips), aff'd, 461 F.2d 1088 (8th Cir. 1972) (per curiam). If Congress intended to foreclose such suits, it could easily have done so in the NLEA or otherwise. See *Hagen* v. *Utah*, 510 U.S. 399, 416 (1994); cf. *Wyeth* v. *Levine*, 555 U.S. 555, 574 (2009) ("If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history."). The fact that Congress has not expressly addressed the application of Section 43(a) of the Lanham Act to food labels therefore casts doubt on the seemingly categorical breadth of the court of appeals' reasoning.

2. Nor can the breadth of the court of appeals' decision be justified on other grounds.

a. In *Schering-Plough Healthcare Products, Inc.* v. *Schwarz Pharma, Inc.*, 586 F.3d 500, 505-509 (2009), the Seventh Circuit held that an ongoing FDA proceeding about alleged misbranding of the subject drug made an action under Section 43(a) of the Lanham Act against the drug's manufacturer unripe and unsuitable for resolution on summary judgment. In that court's view, "FDA

should be given a chance to opine on the proper labeling before a Lanham Act suit is filed, * * * since it has more experience with consumers' understanding of drug labels than judges do." *Id.* at 508-509. The court of appeals below similarly expressed the view that the resolution of petitioner's claim fell within FDA's special competence, and it suggested that petitioner bring its complaints directly to FDA. Pet. App. 12a.

Such considerations—which mirror those underlying the doctrine of primary jurisdiction, see *Reiter* v. *Cooper*, 507 U.S. 258, 268-269 (1993)—lack force here. Most fundamentally, petitioner's claim arises under the Lanham Act, and it does not rely for its success on FDA's regulations (or, therefore, on FDA's application of those regulations). FDA does not administer the Lanham Act, and it has no authority to resolve a competitor's claim of competitive injury due to a misleading label.[4]

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[4] The FDCA's food misbranding provision makes one reference to "unfair competition" in connection with ingredient disclosure, but it is not relevant here: "To the extent that compliance with the requirement[] [to disclose all ingredients in foods with two or more ingredients] * * * results in deception or unfair competition, exemptions shall be established by regulations." 21 U.S.C. 343(i). FDA has promulgated such exemptions, which are now codified at 21 C.F.R. Pt. 101, Subpt. G. FDA elucidated the statutory reference to "unfair competition" when it promulgated the predecessors to those exemption regulations:

> [Because] there may be no feasible way to determine whether nonfunctional trace amounts of some particular substances remain in particular lots of a finished food, * * * label declaration of such ingredients would be false and misleading for those lots which do not contain any remaining traces of such incidental substances. Furthermore, to require lengthy listings of such substances might cause consumers to give undue attention to the essentially meaningless compilations resulting in deception and unfair competition from competing products whose manufactur-

Moreover, the application of primary-jurisdiction-like principles presupposes that the parties may "apply to the [agency] for a ruling." *Reiter*, 507 U.S. at 268 n.3 (citation omitted). But FDA does not accept formal petitions to take a discretionary enforcement action (see 21 C.F.R. 10.30(k)), and its discretionary decision whether to initiate an enforcement action would not be subject to judicial review (see *Heckler* v. *Chaney*, 470 U.S. 821, 837-838 (1985)). Cf. *Alpharma, Inc.* v. *Pennfield Oil Co.*, 411 F.3d 934, 938 (8th Cir. 2005) (concluding that Lanham Act Section 43(a) plaintiff did not need to exhaust administrative remedies because the FDCA creates no administrative procedure for resolving claims of false advertising of animal drugs and because FDA lacks "authority to award the compensatory and punitive damages sought by [the plaintiff]"). Petitioner could petition FDA to undertake a rulemaking to revise its labeling regulations for juice mixtures (21 U.S.C. 371(e)(1)(B); 21 C.F.R. 102.19(a)), but such a rule would not itself redress petitioner's competitive injury. In short, FDA's expertise in this field is not deployed in a way that justifies categorically depriving petitioner of a cause of action under Section 43(a) of the Lanham Act.

b. The court of appeals also treated the absence of an FDA enforcement action against respondent as an affirmative signal that no Lanham Act claim was available.

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ers fail to do as thorough a job of imagining all possible substances which may be present in some trace amount.

38 Fed. Reg. 20,705 (Aug. 2, 1973). The statute thus reflects a narrow concern that FDA should be able to temper label requirements that would otherwise compel manufacturers to put themselves at an unwarranted competitive disadvantage; it is not a broader mandate that FDA police all matters of unfair competition in food labeling.

See Pet. App. 10a-12a. To be sure, affirmative FDA *approval* of specific labeling—as in the prescription drug context, for example, see 21 U.S.C. 355(d)—would preclude a claim under Section 43(a) of the Lanham Act, if that claim rested on grounds that would conflict with a determination underlying the agency's approval. Cf. pp. 17-18, *infra*. But FDA does not approve juice labels, and its failure to initiate an enforcement action cannot be construed as such an approval. See *Chaney*, 470 U.S. at 831 (observing that an agency contemplating enforcement action "must not only assess whether a violation has occurred, but whether agency resources are best spent on this violation or another, whether the agency is likely to succeed if it acts, whether the particular enforcement action requested best fits the agency's overall policies, and, indeed, whether the agency has enough resources to undertake the action at all").

c. Finally, courts have rejected private suits seeking enforcement of agency-administered statutes and regulations "dressed up as a Lanham Act claim." See, *e.g.*, *Cottrell, Ltd.* v. *Biotrol Int'l, Inc.*, 191 F.3d 1248, 1254-1255 (10th Cir. 1999) (rejecting as precluded plaintiff's claim that because defendant's advertising allegedly violated the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*, and regulations thereunder, such advertising was actionable under the Lanham Act). Those courts have concluded that the private right of action under Section 43(a) of the Lanham Act cannot be used to circumvent Congress's determination that provisions of another statute or agency regulations should not, as such, be privately enforceable. Whatever the force of that reasoning, it does not apply here. As we understand it, petitioner does not seek to prove its Lanham Act claim by showing that respond-

ent's juice's label violates the FDCA or FDA's regulations; rather, it seeks to show that the label bears a misrepresentation independently made actionable by the Lanham Act irrespective of the FDCA. Cf. *Cottrell*, 191 F.3d at 1255-1257 (allowing plaintiff to pursue theories on which it had "alleged sufficient facts to support a Lanham Act claim independent of FIFRA").[5]

3. a. Although the court of appeals' preclusion reasoning was too broad, it was correct to recognize that FDA's regulations preclude a Lanham Act challenge to the common name of respondent's juice. The parties do not seriously contest that 21 C.F.R. 102.33 envisions that a blend of juices characterized by flavors of pomegranate and blueberry may be represented as "Pomegranate Blueberry Flavored" (see 21 C.F.R. 102.33(b) and (d)), so long as the common name indicates the presence of other juices by further describing the product as, for example, a "Blend of 5 Juices" (see 21 C.F.R. 102.33(c)). Indeed, the common name of respondent's juice closely parallels examples that FDA's regulations offer as permissible common names for juice mixtures. See pp. 2-3, *supra*.

FDA explained that those naming regulations were calculated "to provide manufacturers with flexibility for labeling products while providing consumers with information that they need to determine the nature of the

---

[5] In the preemption context, this Court has recognized, analogously, that although a State may not supply a private cause of action based solely on a violation of federal statutes that are not privately enforceable, *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) (Medical Device Amendments to the FDCA), a State is permitted to adopt its own regulatory or tort duties that "parallel" (*i.e.*, are the same as) duties under such federal statutes, see, *e.g.*, *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (Medical Device Amendments to the FDCA); *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431, 447-448 (2005) (FIFRA).

product." 58 Fed. Reg. 2920 (Jan. 6, 1993). The agency noted its "aware[ness] of a number of products currently on the market for which the suggested labeling would not inform the consumer that the named juice is present in only a minor amount." *Ibid.* Yet FDA discussed at length why it would not be misleading to describe such a beverage as "flavored" with a non-predominant juice, even while not listing by name or percentage the other juices present. *Id.* at 2918-2921.

Within their limited reach, those naming regulations reflect the agency's balance of competing considerations in a specific setting that could be easily upset by the intrusion of a general private remedy such as that provided under Section 43(a) of the Lanham Act. Cf. *Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 874-886 (2000) (explaining how, in that case, imposition of a general tort duty would frustrate a delicately crafted motor vehicle safety regulation). Success on petitioner's claim that the common name of respondent's juice was misleading would undo what the parties seemingly accept as FDA's regulations' specific pronouncement on that very subject. Accordingly, invocation of the general remedy under Section 43(a) of the Lanham Act specifically for the claim regarding the common name of respondent's juice is not "capable of coexistence" with those regulations, *J. E. M. Ag Supply*, 534 U.S. at 143 (citation omitted), and must give way. Indeed, the clash is particularly acute here because the content of FDA's naming regulations derives largely from the agency's answer to the question of what will and will not mislead juice consumers—essentially the question posed by petitioner's Lanham Act claim.

b. By contrast, petitioner should be free to challenge aspects of respondent's juice's label that are not specifi-

cally addressed by the FDCA or FDA's regulations. In particular, the FDCA and FDA have not specifically addressed "how [respondent] presents the words 'Pomegranate Blueberry' and 'Flavored Blend of 5 Juices' on the product's label." Pet. App. 10a. Petitioner appears to contend that the prominence of the former words relative to the latter obscures the message that FDA believed would be conveyed by designating a characterizing juice as a "flavor." See Pet. 8.

Certainly, the FDCA touches on that issue by providing that a food is misbranded if required label material (such as a juice mixture's common name) "is not prominently placed [on the label] with such conspicuousness * * * as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase." 21 U.S.C. 343(f). But a suit under Section 43(a) of the Lanham Act successfully challenging an inconspicuous disclaimer would tend to *reinforce*, not undo, that requirement. And indeed, FDA specifically cautioned manufacturers who would take advantage of 21 C.F.R. 102.33(b)-(d) about the potential for their labels to mislead. See note 3, *supra*. Because the non-naming aspect of petitioner's Lanham Act claim can easily co-exist with the FDCA and FDA's regulations, the court of appeals erred in concluding it was precluded.

B. The Court Of Appeals' Error Implicates No Developed Circuit Conflict

1. Petitioner contends (Pet. 16-24; Pet. Reply Br. 5-10) that the decision below conflicts with decisions of other courts of appeals in Lanham Act cases. Any conflict is too oblique to justify review. None of the cases petitioner cites concerned the preclusive effect of the FDCA's regulation of food labels and labeling. See *Alpharma*, *supra* (antibiotic animal feed additive regulated

by FDCA's animal drug provisions and regulations thereunder); *Cottrell*, *supra* (cleaning product governed by FIFRA's pesticide provisions and regulations thereunder); *Sandoz Pharm. Corp.* v. *Richardson-Vicks, Inc.*, 902 F.2d 222 (3d Cir. 1990) (cough syrup regulated by FDCA's over-the-counter drug provisions and regulations thereunder, and under the Federal Trade Commission's authority); cf. *Wyeth*, *supra* (addressing preemptive effect of FDCA's name-brand prescription drug provisions and regulations thereunder).

To be sure, some tension may exist between the reasoning in those cases and the reasoning of the decision below. But no square conflict is presented because, as explained (pp. 9-13, *supra*), the court of appeals' error traces principally to its misapprehension of the scope and purpose of the FDCA's food labeling provisions and particular FDA juice-labeling regulations.

2. As for challenges to food labels under Section 43(a) of the Lanham Act, other courts of appeals have proceeded to the merits of such claims. See *PBM Prods., LLC* v. *Mead Johnson & Co.*, 639 F.3d 111 (4th Cir. 2011) (infant formula); *American Italian Pasta Co.* v. *New World Pasta Co.*, 371 F.3d 387 (8th Cir. 2004) (pasta); *Mead Johnson & Co.* v. *Abbott Labs.*, 201 F.3d 883 (7th Cir.) (infant formula), cert. denied, 531 U.S. 917 (2000). But to our knowledge all have done so without addressing the question presented, presumably because that threshold question was not raised (and, indeed, may not have been implicated on the facts of those cases). If the question presented in this case is significant, then the opportunity for beneficial percolation in lower courts exists because claims like petitioner's can be expected to be brought in the future challenging food labels. At the present time, however, in the absence of a conflict of

appellate decisions addressing the availability of a remedy under Section 43(a) of the Lanham Act concerning food labels, the issue does not warrant this Court's review.

C. The Record In This Case Is Unclear Concerning The Nature Of Respondent's Alleged Misrepresentation

An additional feature of this case weighs against review. This case was resolved on summary judgment after full fact and expert discovery. Yet the summary judgment record may be equivocal on the precise misrepresentation that petitioner's Lanham Act claim challenges.

In particular, petitioner's expert testimony that the label of respondent's juice misleads consumers was based on an in-person consumer survey. See Doc. 152-2 Exh. 1 (petitioner's expert's report). That survey was conducted by comparing consumers' reactions to the actual product package with other consumers' reactions to a modified package that removed the words "Pomegranate Blueberry." See *id.* at 1-2. As respondent pointed out to the district court (*e.g.*, Doc. 150, at 2), that survey may simply reflect that some consumers are misled by the *common name* of the juice (which was altered on the modified package). Of course, it may be that the survey reflects that some consumers were misled by the *presentation* on the package of the otherwise non-misleading common name.

That ambiguity in what we take to be petitioner's key evidence is problematic. As explained (pp. 17-19, *supra*), the question of what feature of the label misleads consumers is material to the proper analysis of whether a claim under Section 43(a) of the Lanham Act is precluded. Yet the ambiguity in the record suggests that this case may not properly present the very distinction that

is required for a sound resolution of the question presented. That would be an additional, prudential reason to deny review.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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NOVEMBER 2013

JOINT APPENDIX

RECORD
AND
BRIEFS

Supreme Court, U.S.
FILED
FEB 24 2014
OFFICE OF THE CLERK

No. 12-761

IN THE

Supreme Court of the United States

POM WONDERFUL LLC,

Petitioner,

v.

THE COCA-COLA COMPANY,

Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

JOINT APPENDIX

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U.S. DISTRICT COURT FOR THE
CENTRAL DISTRICT OF CALIFORNIA
(WESTERN DIVISION - LOS ANGELES)

CIVIL DOCKET FOR CASE #:
2:08-cv-06237-SJO-FMO

POM WONDERFUL LLC v. THE COCA COLA COMPANY

Date Filed #	Docket Text
09/22/2008 1	COMPLAINT against Defendants The Coca Cola Company, DOES 1-10, inclusive. (Filing fee $ 350 PAID.) Jury Demanded., filed by Plaintiff Pom Wonderful LLC. (et) (ds). (Entered: 09/25/2008)
	* * *
11/26/2008 8	NOTICE OF MOTION AND MOTION to Dismiss Case *Pursuant to FRCP 12(b)(6)* filed by Defendant The Coca Cola Company. Motion set for hearing on 1/5/2009 at 10:00 AM before Judge S. James Otero. (Dworsky, Marc) (Entered: 11/26/2008)
	* * *
12/15/2008 11	OPPOSITION re: MOTION to Dismiss Case *Pursuant to FRCP 12(b)(6)* 8 filed by Plaintiff Pom Wonderful LLC. (Campbell, Mark) (Entered: 12/15/2008)
	* * *
12/29/2008 13	REPLY in support of MOTION to Dismiss Case *Pursuant to FRCP*

12(b)(6) 8 filed by Defendant The Coca Cola Company. (Dworsky, Marc) (Entered: 12/29/2008)

* * *

02/10/2009 25 ORDER by Judge S. James Otero, re MOTION to Dismiss Case *Pursuant to FRCP 12(b)(6)* 8. *Coca Cola's Motion is GRANTED IN PART, DENIED IN PART.* (bp) (Entered: 02/10/2009)

* * *

03/02/2009 27 ANSWER JURY DEMAND. *DEFENDANT'S ANSWER TO COMPLAINT; DEMAND FOR JURY TRIAL* filed by Defendant The Coca Cola Company. (Bern, Martin) (Entered: 03/02/2009)

* * *

07/27/2009 53 FIRST AMENDED COMPLAINT against defendants' The Coca Cola Company, DOES amending Complaint (Discovery) 1, filed by plaintiff Pom Wonderful LLC (bp) (Additional attachment(s) added on 7/29/2009: # 1 FAC) (bp). (Entered: 07/29/2009)

* * *

08/10/2009 55 NOTICE OF MOTION AND MOTION to Dismiss First Amended Complaint *Pursuant to Fed. R. Civ. P. 12(b)(6); Memorandum of Points and Authorities in Support Thereof* filed by Defendant The Coca Cola Company. Motion set for hearing on 9/8/2009 at

10:00 AM before Judge S. James Otero. (Attachments: # 1 Declaration of Martin D. Bern) (Bern, Martin) (Entered: 08/10/2009)

* * *

08/26/2009 58 OPPOSITION re: MOTION to Dismiss First Amended Complaint *Pursuant to Fed. R. Civ. P. 12(b)(6); Memorandum of Points and Authorities in Support Thereof* MOTION to Dismiss First Amended Complaint *Pursuant to Fed. R. Civ. P. 12(b)(6); Memorandum of Points and Authorities in Support Thereof* 55 filed by Plaintiff Pom Wonderful LLC. (Attachments: # 1 Exhibit A) (Silverman, Daniel) (Entered: 08/26/2009)

09/01/2009 59 REPLY In Support Of MOTION to Dismiss First Amended Complaint *Pursuant to Fed. R. Civ. P. 12(b)(6); Memorandum of Points and Authorities in Support Thereof* MOTION to Dismiss First Amended Complaint *Pursuant to Fed. R. Civ. P. 12(b)(6); Memorandum of Points and Authorities in Support Thereof* 55 *Reply Memorandum of Points and Authorities in Support of Motion to Dismiss First Amended Complaint Pursuant to Fed. R. Civ. P. 12(b)(6)* filed by Defendant The Coca Cola Company. (Dworsky, Marc) (Entered: 09/01/2009)

09/09/2009 60 MINUTES (IN CHAMBERS): MOTION to Dismiss First Amended Com-

plaint Pursuant to Fed.R.Civ.P. 12(b)(6); Memorandum of Points and Authorities in Support thereof filed by Defendant The Coca Cola Company by Judge S. James Otero: taking under advisement 55 Motion to Dismiss (bp) (Entered: 09/09/2009)

09/09/2009 61 MINUTES (IN CHAMBERS): MOTION to Dismiss First Amended Complaint Pursuant to Fed.R.Civ.P. 12(b)(6); Memorandum of Points and Authorities in Support thereof filed by Defendant The Coca Cola Company. 55 filed 8/10/09. The Court takes the motion under submission by Judge S. James Otero: taking under advisement 55 Motion to Dismiss (bp) (Entered: 09/09/2009)

* * *

09/15/2009 65 MINUTES (IN CHAMBERS): ORDER DENYING DEFENDANT'S MOTION TO DISMISS FIRST AMENDED COMPLAINT PURSUANT TO FED.R.CIV.P.12(b)(6) [Docket No. 55]. Coca Cola's Motion is DENIED. Pom may pursue discovery in furtherance of its Lanham Act claim and Pom's state law claims are not barred for lack of standing. Defendant has until September 30, 2009 to answer the complaint by Judge S. James Otero: denying 55 Motion to Dismiss (bp) (Entered: 09/15/2009)

* * *

09/30/2009 70 ANSWER to Amended Complaint 53; *Demand for Jury Trial* filed by Defendant The Coca Cola Company. (Bern, Martin) (Entered: 09/30/2009)

* * *

12/28/2009 149 NOTICE OF MOTION AND MOTION for Partial Summary Judgment as to Defendant's Affirmative Defenses of Safe Harbor and Compliance With Laws filed by Plaintiff Pom Wonderful LLC. Motion set for hearing on 1/25/2010 at 10:00 AM before Judge S. James Otero. (Attachments: # 1 Statement of Uncontroverted Facts and Conclusions of Law ISO Plaintiff's Motion for Partial Summary Judgment, # 2 Declaration of Daniel A. Beck ISO Plaintiff's Motion for Partial Summary Judgment, # 3 Proposed Order) (Silverman, Daniel) (Entered: 12/28/2009)

12/28/2009 150 NOTICE OF MOTION AND MOTION for Summary Judgment as to First Amended Complaint filed by Defendant The Coca Cola Company. Motion set for hearing on 1/25/2010 at 10:00 AM before Judge S. James Otero. (Attachments: # 1 Proposed Order) (Jones, Kenneth) (Entered: 12/28/2009)

* * *

12/28/2009 152 DECLARATION of Steven A. Zalesin in Support of MOTION for Summary Judgment as to First Amended Complaint 150 filed by Defendant The Coca

Cola Company. (Attachments: # 1 Exhibit 1 Report of Dr. E. Deborah Jay, # 2 Exhibit 2 NAD Decision 9.22.09, # 3 Declaration 3 - Judge Matz's Order re Motion to Dismiss 06.23.09, # 4 Exhibit 4 - Judge Pregerson's Order re Motion to Dismiss 20 Dismiss 10.21.09, # 5 Exhibit 5 - Judge Fischer's Order re Motion to Dismiss 10.21.09, # 6 Exhibit 6 - Judge Matz's Order re Motion for Judgment [o]n the Pleadings 12.21.09)(Jones, Kenneth) (Entered: 12/28/2009)

12/28/2009 153 DECLARATION of Charles Torrey in Support of MOTION for Summary Judgment as to First Amended Complaint 150 filed by Defendant The Coca Cola Company. (Attachments: # 1 Exhibit 1 Photos of Minute Maid Bottles and Label, # 2 Exhibit 2 Catalina Coupons, # 3 Exhibit 3 Promotional Materials 1 of 3, # 4 Exhibit 3 - Promotional Materials 2 of 3, # 5 Exhibit 3 Promotional Materials 3 of 3, # 6 Exhibit 4 Print Ads, # 7 Exhibit 5 Television Ads, # 8 Exhibit 6 - Website Ads Etc.) (Jones, Kenneth) (Entered: 12/28/2009)

* * *

12/30/2009 157 NOTICE OF LODGING filed *by Defendant The Coca-Cola Company* re MOTION for Summary Judgment as to First Amended Complaint 150 (Attachments: # 1 Proposed Order State-

ment of Uncontroverted Facts and Proposed Conclusions of Law in Support of Motion for Summary Judgment) (Jones, Kenneth) (Entered: 12/30/2009)

* * *

01/11/2010 160 NOTICE of Manual Filing filed by Plaintiff Pom Wonderful LLC of Application to Seal; Plaintiff's Opposition to Defendant's Motion for Summary Judgment; Plaintiff's Statement of Genuine Issues of Material Fact and Proposed Conclusions of Law; Exhibits E-Q to the Declaration of Daniel S. Silverman; [Proposed] Order Granting Application to Seal; Proof of Service. (Silverman, Daniel) (Entered: 01/11/2010)

01/11/2010 161 OPPOSITION in Opposition to re: MOTION for Partial Summary Judgment as to Defendant's Affirmative Defenses of Safe Harbor and Compliance With Laws 149 filed by Defendant The Coca Cola Company. (Attachments: # 1 Declaration Steven A. Zalesin in Opposition to Motion for Partial Summary Judgment, # 2 Exhibit 1 Excerpt from Deposition of E. Deborah Jay, # 3 Exhibit 2 Copy of Exhibit A to Declaration of Christopher Van Gundy filed in the Ocean Spray Action) (Jones, Kenneth) (Entered: 01/11/2010)

01/11/2010 162 STATEMENT of Genuine Issues in Support of Opposition to MOTION for Partial Summary Judgment as to De-

fendant's Affirmative Defenses of Safe Harbor and Compliance With Laws 149 filed by Defendant The Coca Cola Company. (Jones, Kenneth) (Entered: 01/11/2010)

01/11/2010 163 MEMORANDUM in Opposition to MOTION for Summary Judgment as to First Amended Complaint 150 filed by Plaintiff Pom Wonderful LLC. (Attachments: # 1 Statement of Genuine Issues of Material Fact and Proposed Conclusions of Law, # 2 Declaration of Daniel S. Silverman with Exhibits A-D, # 3 Declaration of E. Deborah Jay) (Silverman, Daniel) (Entered: 01/11/2010)

* * *

01/15/2010 173 REPLY In Support Of MOTION for Partial Summary Judgment as to Defendant's Affirmative Defenses of Safe Harbor and Compliance With Laws 149 filed by Plaintiff Pom Wonderful LLC. (Silverman, Daniel) (Entered: 01/15/2010)

01/15/2010 174 REPLY In Support of MOTION for Summary Judgment as to First Amended Complaint 150 filed by Defendant The Coca Cola Company. (Attachments: # 1 Declaration of Travis Tu, # 2 Declaration Charles Torrey, # 3 Declaration Dr. Ran Kivetz, # 4 Exhibit A to Kivetz Declaration, # 5 Exhibit 1 to Torrey Declaration, # 6 Evidentiary Objections, # 7 Reply Separate

Statement, # 8 Notice of Manual Filing, # 9 Exhibit 1-4 to Tu Declaration) (Sands, Cynthia) (Entered: 01/15/2010)

01/15/2010 175 OBJECTIONS to Response in Support of Motion 168 filed by Plaintiff Pom Wonderful LLC. (Silverman, Daniel) (Entered: 01/15/2010)

* * *

01/22/2010 182 MINUTES (IN CHAMBERS): ORDER by Judge S. James Otero. The parties are advised that MOTION for Partial Summary Judgment Re: Defendant's Affirmative Defenses of Safe Harbor and Compliance With Laws 149 filed by Plaintiff Pom Wonderful LLC, AND the MOTION for Summary Judgment as to First Amended Complaint filed by Defendant The Coca Cola Company 150, scheduled for hearing on January 25, 2010, are taken under submission. Accordingly, the hearing date is vacated. Order will issue. (sch) (Entered: 01/22/2010)

* * *

02/02/2010 202 NOTICE OF MOTION AND MOTION IN LIMINE Four (4) to Exclude EVIDENCE AND TESTIMONY REGARDING CONSUMER COMMENTS [REDACTED] *dated February 2, 2010* filed by Defendant The Coca Cola Company. Motion set for hearing on 3/9/2010 at 10:00 AM before

Judge S. James Otero. (Jones, Kenneth) (Entered: 02/02/2010)

* * *

02/04/2010 228 SEALED DOCUMENT - Plaintiff's Memorandum of Points and Authorities in Opposition to Defendant's Motion for Summary Judgment. (mat) (Entered: 02/05/2010)

02/04/2010 229 SEALED DOCUMENT Plaintiff's Statement of Genuine Issues of Material Fact and Proposed Conclusions of Law in Opposition to Defendant's Motion for Summary Judgment. (mat) (Entered: 02/05/2010)

02/04/2010 230 SEALED DOCUMENT - Exhibits E-Q to the Declaration of Daniel S. Silverman in Opposition to Defendant's Motion for Summary Judgment. (mat) (Additional attachment(s) added on 2/5/2010: Part 2) (mat). (Entered: 02/05/2010)

* * *

02/04/2010 239 SEALED DOCUMENT Defendant's Reply Statement in Response to Plaintiff's (1) Statement of Genuine Issues and (2) Statement of Additional Material Facts Related to Defendant's Motion for Summary Judgment. (mat) (Entered: 02/09/2010)

* * *

02/09/2010 257 MEMORANDUM in Opposition to MOTION IN LIMINE Four (4) to Ex-

clude EVIDENCE AND TESTIMONY REGARDING CONSUMER COMMENTS [REDACTED] *dated February 2, 2010* MOTION IN LIMINE Four (4) to Exclude EVIDENCE AND TESTIMONY REGARDING CONSUMER COMMENTS [REDACTED] *dated February 2, 2010* 202 *(Public Redacted Version)* filed by Plaintiff Pom Wonderful LLC. (Beck, Daniel) (Entered: 02/09/2010)

* * *

02/16/2010 280 REPLY in support of MOTION IN LIMINE Four (4) to Exclude EVIDENCE AND TESTIMONY REGARDING CONSUMER COMMENTS [REDACTED] *dated February 2, 2010* MOTION IN LIMINE Four (4) to Exclude EVIDENCE AND TESTIMONY REGARDING CONSUMER COMMENTS [REDACTED] *dated February 2, 2010* 202 filed by Defendant The Coca Cola Company. (Attachments: # 1 Declaration of Nancy Tyndal in Support, # 2 Exhibit 1 Excerpts from Tyndal Deposition) (Jones, Kenneth) (Entered: 02/16/2010)

* * *

05/05/2010 360 ORDER GRANTING IN PART, DENYING IN PART DEFENDANT'S MOTION FOR SUMMARY JUDGMENT PURSUANT TO FED. R. CIV. P. 56; DENYING PLAIN-

TIFF'S MOTION FOR PARTIAL SUMMARY ADJUDICATION RE: DEFENDANT'S AFFIRMATIVE DEFENSES OF SAFE HARBOR AND COMPLIANCE WITH LAWS 149, 150 by Judge S. James Otero (lc) (Entered: 05/05/2010)

* * *

05/24/2010 376 FINAL JUDGMENT is hereby entered in favor of Defendant The Coca-Cola Company and against plaintiff Pom Wonderful LLC (MD JS-6, Case Terminated). (lc) (Entered: 05/24/2010)

05/28/2010 377 NOTICE OF APPEAL to the 9th CCA filed by Plaintiff Pom Wonderful LLC. Appeal of Order 25, Judgment 376, Order on Motion for Partial Summary Judgment, Order on Motion for Summary Judgment, 360. (Filing fee $455, receipt number 0973-7023144.) (Beck, Daniel) (Entered: 05/28/2010)

* * *

08/17/2012 389 MANDATE of 9th CCA filed re: Notice of Appeal to 9th Circuit Court of Appeals, 377, CCA # 10-55861. We affirm the district court's summary judgment to the extent it barred Pom's Lanham Act claim with respect to Pomegranate Blueberry's name and labeling. We vacate the summary judgment to the extent it ruled that Pom lacked statutory standing on its UCL and FAL claims; we remand so that the

district court can rule on the state claims in accordance with this opinion. Affirmed in part, Vacated in part, and Remanded. Each party shall bear its own costs. Mandate received in this district on 8/17/12. (car) (Entered: 08/23/2012)

* * *

01/07/2013 399 NOTICE OF MOTION AND MOTION for Summary Judgment as to all remaining claims alleged in the First Amended Complaint filed by defendant The Coca Cola Company. (Attachments: # 1 Statement of Uncontroverted Facts, # 2 Proposed Order) (Zalesin, Steven) (Entered: 01/07/2013)

* * *

01/18/2013 402 NOTICE of Manual Filing filed by Plaintiff Pom Wonderful LLC of (1) Application to seal and proposed order; (2) Plaintiff's Memorandum of Points and Authorities in Opposition to Defendant's Motion for Summary Judgment; (3) Plaintiff's Statement of Genuine Issues; (4) Declaration of Daniel A. Beck; and (5) Declaration of E. Deborah Jay. (Beck, Daniel) (Entered: 01/18/2013)

* * *

01/18/2013 405 DECLARATION of E. Deborah Jay in opposit[]ion MOTION for Summary Judgment as to all remaining claims alleged in the First Amended Complaint

399 filed by Plaintiff Pom Wonderful LLC. (Attachments: # 1 PART 2) (lc) (Entered: 01/24/2013)

* * *

01/25/2013 408 REPLY in support of MOTION for Summary Judgment as to all remaining claims alleged in the First Amended Complaint 399 filed by Defendant The Coca Cola Company. (Jones, Kenneth) (Entered: 01/25/2013)

* * *

01/25/2013 413 SEALED DOCUMENT PLAINTIFF'S STATEMENT of Genuine Issues of Material Fact and Proposed Conclusions of Law in Opposition to Defendant's Motion for Summary Judgment. (mat) (Entered: 02/01/2013)

01/25/2013 414 SEALED DOCUMENT - EXHIBITS E-Q to the Declaration of Daniel A. Beck in Opposition to Defendant's Motion for Summary Judgment. (Attachments: Part 2) (mat) (Entered: 02/01/2013)

01/25/2013 415 SEALED DOCUMENT PLAINTIFF'S MEMORANDUM of Points and Authorities in Opposition to Defendant's Motion for Summary Judgment. (mat) (Entered: 02/01/2013)

* * *

02/13/2013 417 MINUTES (IN CHAMBERS) by Judge S. James Otero: The Court GRANTS Defendant The Coca Cola

Company's Motion for Summary Judgment on Plaintiff's remaining State Law Claims 399 . This matter shall close. MD JS-6. Case Terminated. (lc) (Entered: 02/13/2013)

03/13/2013 418 ORDER that Coca-Cola's motion for summary judgment is GRANTED in all respects 399 by Judge S. James Otero (lc) (Entered: 04/19/2013)

* * *

GENERAL DOCKET
UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

COURT OF APPEALS DOCKET #: 10-55861

POM WONDERFUL LLC v. THE COCA COLA COMPANY

05/28/2010	1	DOCKETED CAUSE AND ENTERED APPEARANCES OF COUNSEL. SEND MQ: No. The schedule is set as follows: Transcript ordered by 06/28/2010. Transcript due 09/27/2010. Appellant Pom Wonderful LLC opening brief due 11/08/2010. Appellee The Coca Cola Company answering brief due 12/08/2010. Appellant's optional reply brief is due 14 days after service of the answering brief. [7354201] (JN)
		* * *
11/08/2010	9	Submitted (ECF) Opening brief for review. Submitted by Appellant Pom Wonderful LLC. Date of service: 11/08/2010. [7538782] (SPW)
11/09/2010	10	Filed clerk order: The opening brief [9] submitted by Pom Wonderful LLC is filed. Within 7 days of the filing of this order, filer is ordered to file 7 copies of the brief in paper format, with a blue cover, accompanied by certification, attached to the end of each copy of the brief, that the brief is identical

to the version submitted electronically. [7540155] (LA)

11/09/2010 11 Filed Appellant Pom Wonderful LLC excerpts of record in 2 volumes. Served on 11/08/2010. [7544165] (LA)

* * *

12/22/2010 14 Submitted (ECF) Answering brief for review. Submitted by Appellee The Coca Cola Company. Date of service: 12/22/2010. [7589559]–[COURT UPDATE: Replaced PDF of brief with corrected version. Resent NDA. 12/23/2010 by TW] (SAZ)

12/23/2010 15 Filed clerk order: The answering brief [14] submitted by The Coca Cola Company is filed. Within 7 days of the filing of this order, filer is ordered to file 7 copies of the brief in paper format, with a red cover, accompanied by certification, attached to the end of each copy of the brief, that the brief is identical to the version submitted electronically. [7590762] (LA)

12/27/2010 17 Filed Appellee The Coca Cola Company supplemental excerpts of record on appeal in 1 volume. [7594284] (LA)

* * *

01/24/2011 19 Submitted (ECF) Reply brief for review. Submitted by Appellant Pom Wonderful LLC. Date of service: 01/24/2011. [7622353] (SPW)

01/24/2011	20	Filed clerk order: The reply brief [19] submitted by Pom Wonderful LLC is filed. Within 7 days of the filing of this order, filer is ordered to file 7 copies of the brief in paper format, with a gray cover, accompanied by certification, attached to the end of each copy of the brief, that the brief is identical to the version submitted electronically. [7622605] (LA)
		* * *
02/08/2012	38	ARGUED AND SUBMITTED TO DOROTHY W. NELSON, DIARMUID F. O'SCANNLAIN and N. RANDY SMITH. [8061127] (FB)
		* * *
05/17/2012	42	FILED OPINION (DOROTHY W. NELSON, DIARMUID F. O'SCANNLAIN and N. RANDY SMITH) AFFIRMED IN PART, VACATED IN PART, AND REMANDED. Each party shall bear its own costs. Judge: DFO Authoring, FILED AND ENTERED JUDGMENT. [8181853] (RP)
		* * *
06/29/2012	45	Filed (ECF) Appellant Pom Wonderful LLC petition for panel rehearing and petition for rehearing en banc (from 05/17/2012 opinion). Date of service: 06/29/2012. [8233934] (SPW)
07/03/2012	46	Filed order (DOROTHY W. NELSON, DIARMUID F.

O'SCANNLAIN and N. RANDY SMITH): The Defendant–Appellee is directed to file a response to the petition for rehearing and for rehearing en banc filed with this court on June 29, 2012. The response shall not exceed 15 pages or 4200 words and shall be filed within 21 days of the date of this order. Parties who are registered for ECF must file the response electronically without submission of paper copies. Parties who are not registered ECF filers must file the original response plus 50 paper copies. [8236722] (AF)

07/24/2012 47 Filed (ECF) Appellee The Coca-Cola Company response to Combo PFR Panel and En Banc (ECF Filing), Combo PFR Panel and En Banc (ECF Filing) for panel and en banc rehearing, for panel and en banc rehearing (statistical entry). Date of service: 07/24/2012. [8261002]. (SAZ)

08/08/2012 48 Filed order (DOROTHY W. NELSON, DIARMUID F. O'SCANNLAIN and N. RANDY SMITH) The panel has voted to deny Pom Wonderful LLC's Petition for Rehearing and for Rehearing En Banc. The panel has voted unanimously to deny the petition for rehearing. Judges O'Scannlain and N.R. Smith have voted to deny the petition for rehearing en banc, and Judge Nelson has so recommended. The full court has

		been advised of the petition for rehearing en banc, and no active judge has requested a vote on whether to rehear the matter en banc. Fed. R. App. P. 35. Pom Wonderful LLC's Petition for Rehearing and for Rehearing En Banc is DENIED. [8280582] (SM)
08/17/2012	49	MANDATE ISSUED. (DWN, DFO and NRS) [8290419] (TB)
		* * *
01/13/2014	54	Received notice from the Supreme Court. Petition for certiorari GRANTED on 01/10/2014. Justice Breyer and Justice Alito took no part in the consideration or decision of this petition. Supreme Court Number 12-761. [8934979] (RR)

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

POM WONDERFUL LLC,
a Delaware limited liability company,
Plaintiff,

v.

THE COCA COLA COMPANY,
a Delaware corporation; and DOES 1-10, inclusive,
Defendants.

Case No. CV08-06237
September 22, 2008

COMPLAINT FOR FALSE ADVERTISING UNDER LANHAM ACT 43(A); FALSE ADVERTISING UNDER CALIFORNIA BUSINESS & PROFESSIONS CODE § 17500, ET SEQ.; UNFAIR COMPETITION UNDER CALIFORNIA BUSINESS & PROFESSIONS CODE § 17200, ET SEQ.

DEMAND FOR JURY TRIAL

Plaintiff POM WONDERFUL LLC ("Pom Wonderful" or "Plaintiff") hereby alleges as follows:

PARTIES

1. Plaintiff Pom Wonderful is a Delaware limited liability company with its principal place of business in Los Angeles, California.

2. On information and belief, defendant The Coca Cola Company ("Coca Cola") is a Delaware corporation with its principal place of business in Atlanta, Georgia.

3. Plaintiff is not aware of the true names and capacities of the defendants identified herein as Does 1 through 10, inclusive, and therefore fictitiously names said defendants. Plaintiff will amend this Complaint to allege the true names and capacities of these fictitiously named defendants when their identities are ascertained.

4. Plaintiff is informed and believes, and thereon alleges, that Coca Cola and each of the fictitiously named Doe defendants (collectively "Defendants") were in some manner responsible for the acts alleged herein and the harm, losses and damages suffered by Plaintiff as alleged hereinafter. Plaintiff is also informed and believes that, while participating in such acts, each Defendant was the agent, alter ego, conspirator, and aidor and abettor of the other Defendants and was acting in the course and scope of such agency and/or acted with the permission, consent, authorization or ratification of the other Defendants.

5. As described further below, Coca Cola conducts business and manufactures and/or distributes products in the greater Los Angeles area, and throughout the United States.

JURISDICTION AND VENUE

6. This action arises under 15 U.S.C. § 1125(a) and the statutory law of the State of California. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §1331 (federal question), 15 U.S.C. § 1121 (Lanham Act claims) and 28 U.S.C. §1367 (supplemental jurisdiction).

7. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and 1400 because a substantial part of

the events or omissions giving rise to the claims occurred in this District.

FACTUAL ALLEGATIONS COMMON TO ALL CLAIMS

8. This action seeks redress for Coca Cola's deliberate and unlawful false and misleading representations regarding its Minute Maid Enhanced Pomegranate Blueberry product ("Pomegranate Blueberry Product"), which has been packaged, marketed and sold by Coca Cola based on the representation that the primary ingredients in the product are pomegranate and blueberry juice, when, in fact, the primary ingredients are actually apple and grape juice.

9. This action also seeks redress for the unfair, unlawful and fraudulent business practices of all Defendants, each of whom have participated in making the false advertising claims relating to Coca Cola's Pomegranate Blueberry Product in California and nationwide.

I. POM WONDERFUL

10. Plaintiff is the largest grower and distributor of pomegranates and pomegranate juice in the United States.

11. Plaintiff produces, markets and sells POM WONDERFUL® brand bottled pomegranate juice, and various pomegranate juice blends including a pomegranate blueberry blend. Pom Wonderful has been bottling, selling and marketing its juice products since 2002.

12. When Pom Wonderful began the development and distribution of POM WONDERFUL® juice, it invested millions of dollars in researching the nutritional

qualities and health benefits of pomegranate juice, an investment that continues to this day. Pom Wonderful has consulted with world-renowned scientists, including a Nobel laureate, and underwrites major research studies, many of which are published in well-known and prestigious peer-reviewed scientific and medical journals.

13. Scientists have discovered that pomegranate juice has very high levels of unique polyphenols, antioxidants that are particularly effective at neutralizing free radicals, preventing oxidation of LDL cholesterol (the "bad" cholesterol) and plaque build-up in the blood vessels, and preserving nitric oxide, a key chemical in the body for regulating blood flow and maintaining vessel health.

14. A key element of Pom Wonderful's marketing campaign has been its concentration on the health benefits associated with pomegranates and pomegranate juice, and its emphasis on the high level of antioxidants contained in POM WONDERFUL® brand juice.

15. Through its investment of millions of dollars to research and promote the nutritional qualities and health benefits associated with pomegranate juice, Plaintiff largely created the burgeoning market for genuine pomegranate juice that exists today. POM Wonderful's pomegranate juice has, in only six short years, eclipsed all other products in its market segment of super premium juices to take the #1 spot nationwide in supermarket sales, as well as the #1 spots in the key geographic regions of Los Angeles, Chicago, New York, among many others. POM Wonderful's annual supermarket sales have, incredibly, gone from zero to well over $70 million in that same period.

16. Plaintiff's success has been both good and bad for consumers. On the one hand, consumers have been made aware of the nutritional qualities and health benefits of 100 percent pomegranate juice. On the other hand, unscrupulous competitors have set out to cash in on Plaintiff's success by marketing and selling to consumers products labeled as "pomegranate juice," that in fact contain little or no actual pomegranate juice. Coca Cola is one such competitor.

II. COCA COLA AND ITS FALSE ADVERTISING OF ITS POMEGRANATE BLUEBERRY PRODUCT

17. Coca Cola markets and sells various bottled juice products under such brands as, among others, Odwalla and Minute Maid, and is currently one of Plaintiff's primary competitors in the bottled pomegranate juice market. Coca Cola is based in Atlanta, Georgia and, Plaintiff is informed and believes, markets, distributes and sells its products, including its Pomegranate Blueberry Product, in Los Angeles County and throughout the United States.

18. In September 2007, Coca Cola announced the addition of a new "Minute Maid® Pomegranate Blueberry" product to its line of "Minute Maid Enhanced Juices" targeting "the health-conscious shopper."

19. Like the pomegranate, in recent years the blueberry has become a staple for health conscious consumers because of its high antioxidant capacity. Thus, Coca Cola's Pomegranate Blueberry Product purports to combine two of nature's most powerful antioxidants into a single "Enhanced Juice" product. In fact, the main ingredients in Coca Cola's Pomegranate Blueberry Product are neither pomegranate nor blueberry juice, but rather, apple and grape juice.

20. Notwithstanding that Coca Cola's product actually contains little pomegranate or blueberry juice, Coca Cola labels its product as "Pomegranate Blueberry" juice. Attached as "Exhibit A" are true and correct copies of photographs of Coca Cola's Pomegranate Blueberry Product. In addition to the claims on the product itself, Coca Cola also maintains a website at <minutemaid.com> that prominently advertises and markets Coca Cola's product as "Minute Maid Enhanced Pomegranate Blueberry" juice. Attached as "Exhibit B" is a true and correct copy of Coca Cola's website advertising its Pomegranate Blueberry Product.

21. Coca Cola has also advertised its Pomegranate Blueberry Product in commercial spots aired during highly rated television shows such as American Idol. Plaintiff is informed and believes that Coca Cola has engaged in other forms of marketing and advertising of its Pomegranate Blueberry Product targeting consumers throughout the United States.

22. Purchasers of Coca Cola's product are likely to be misled and deceived by Coca Cola's product labeling, marketing and advertising. By name alone, one would expect that the primary ingredients in Coca Cola's Pomegranate Blueberry Product are pomegranate and blueberry juice. However, pomegranate juice ranks

third, by volume, behind apple and grape juice in Coca Cola's Pomegranate Blueberry Product. Blueberry juice is found in even smaller amounts, ranking fifth among the ingredients found in Coca Cola's product.

23. Coca Cola's false and misleading advertising of its Pomegranate Blueberry Product is damaging to the reputation and goodwill of Plaintiff and is damaging to the consuming public. These false and misleading representations are designed to entice consumers to purchase Coca Cola's product over Plaintiff's products. Specifically, Coca Cola's false and misleading representations regarding the primary ingredients of its product imply that its product is of the same composition and quality of actual pomegranate blueberry juices such as Plaintiff's pomegranate blueberry juice, when in fact Coca Cola has substituted much of the valuable and beneficial substance of pure pomegranate and blueberry juice with economically and nutritionally inferior juices such as apple and grape.

24. Because the cost to produce Coca Cola's product containing economically inferior components is far less than the cost to produce actual pomegranate blueberry juice (*i.e.*, a juice product whose primary ingredients are actually pomegranate and blueberry juice), Coca Cola can charge less for its product than competitors, including Plaintiff, while reaping a substantial profit. In this way, Coca Cola entices consumers who would otherwise buy Plaintiff's product to buy its product instead. In doing so, Coca Cola wrongfully tricks consumers into thinking that they are getting a similar product (*i.e.*, all natural pomegranate blueberry juice with all of its associated health benefits) for a lower price, when in fact they are getting an economically and nutritionally inferior product.

25. The natural, probable and foreseeable result of Coca Cola's wrongful conduct has been to cause confusion, deception and mistake in the pomegranate blueberry juice market as a whole, to deprive Plaintiff of business and goodwill, and to injure Plaintiff's relationships with existing and prospective customers.

26. Plaintiff is informed and believes that Coca Cola's wrongful conduct has resulted in increased sales of Coca Cola's own Pomegranate Blueberry Product while hindering the sales of Plaintiff's pomegranate juice products and damaging Plaintiff's goodwill. Plaintiff has sustained and will sustain damages as a result of Coca Cola's wrongful conduct.

FIRST CLAIM FOR RELIEF

(False Advertising Under Lanham Act § 43(a), 15 U.S.C. 1125(a) Against All Defendants)

27. Plaintiff incorporates by reference Paragraphs 1 through 26 above as though fully set forth herein.

28. Upon information and belief Defendants have made and distributed, in interstate commerce and in this District, advertisements that contain false or misleading statements of fact regarding their products. These advertisements contain actual misstatements and/or misleading statements and failures to disclose, including, among others, the statement that Defendants' product consists primarily of pomegranate and blueberry juice.

29. Upon information and belief, these false statements actually deceive, or have a tendency to deceive, a substantial segment of Plaintiff's customers and potential customers. This deception is material in that it is likely to influence the purchasing decisions of Plaintiff's customers.

30. Defendants' false and misleading advertising statements and omissions injure both consumers and Plaintiff.

31. Defendants' false and misleading advertising statements and omissions violate the Lanham Act § 43(a), 15 U.S.C. §1125(a).

32. Defendants have caused, and will continue to cause, immediate and irreparable injury to Plaintiff, including injury to its business, reputation, and goodwill, for which there is no adequate remedy at law. As such, Plaintiff is entitled to an injunction under 15 U.S.C. §1116 restraining Defendants, their agents, employees, representatives and all persons acting in concert with them from engaging in further acts of false advertising, and ordering removal of all Defendants' false advertisements.

33. Pursuant to 15 U.S.C. §1117, Plaintiff is entitled to recover from Defendants the damages sustained by Plaintiff as a result of Defendants' acts in violation of Lanham Act § 43(a). Plaintiff is at present unable to ascertain the full extent of the monetary damages it has suffered by reason of Defendants' acts.

34. Pursuant to 15 U.S.C. §1117, Plaintiff is further entitled to recover from Defendants the gains, profits and advantages that they have obtained as a result of their acts. Plaintiff is at present unable to ascertain the full amount of the gains, profits and advantages Defendants have obtained by reason of their acts.

35. Pursuant to 15 U.S.C. §1117, Plaintiff is further entitled to recover the costs of this action. Moreover, Plaintiff is informed and believes, and on that basis alleges, that Defendants' conduct was undertaken willfully and with the intention of causing confusion, mistake

or deception, making this an exceptional case entitling Plaintiff to recover additional damages and reasonable attorneys' fees.

SECOND CLAIM FOR RELIEF

(False Advertising Under Cal. Bus. & Prof. Code § 17500 Against All Defendants)

36. Plaintiff incorporates by reference Paragraphs 1 through 35 above as though fully set forth herein.

37. Defendants knew or in the exercise of reasonable care should have known that their publicly disseminated statements and omissions relating to their Pomegranate Blueberry Product were false or misleading. Defendants' false advertising statements and omissions injure consumers and Plaintiff. Defendants' false and misleading statements include, among others, that Defendants' product consists primarily of pomegranate and blueberry juice.

38. By making such untrue or misleading statements, Defendants have engaged in false advertising in violation of the statutory law of the state of California, Cal. Bus. & Prof. Code §17500, *et seq.*

39. By reason of Defendants' conduct, Plaintiff has suffered injury in fact and has lost money or property.

40. Defendants have caused, and will continue to cause, immediate and irreparable injury to Plaintiff, including injury to its business, reputation, and goodwill, for which there is no adequate remedy at law. Plaintiff is entitled to an injunction restraining Defendants, their agents, employees, representatives and all persons acting in concert with them from engaging in further such acts, and forbidding Defendants from advertising their Pomegranate Blueberry Product as primar-

ily containing pomegranate and blueberry juice, and from making other false statements in connection with the product.

41. Plaintiff is further entitled to a restitutionary recovery from Defendants.

THIRD CLAIM FOR RELIEF

(Statutory Unfair Competition - Cal. Bus. & Prof. Code §17200, *et seq.* Against All Defendants)

42. Plaintiff incorporates by reference Paragraphs 1 through 41 above as though fully set forth herein.

43. Defendants have made, published, disseminated, and circulated false, deceptive, and misleading statements, representations, and advertisements in California misrepresenting the nature, quality, and characteristics of their Pomegranate Blueberry Product with the intent of selling, distributing, and increasing the consumption of, and interest in, their Pomegranate Blueberry Product.

44. Defendants' conduct as alleged herein constitutes unfair competition in that such acts were and are unlawful, unfair, deceptive and/or fraudulent business acts or practices in violation of California Business & Professions Code §17200, *et seq.*

45. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff has suffered injury in fact, which losses include damage to Plaintiff's good will with its existing, former and potential customers. Defendants' conduct has also caused damage to consumers.

46. These wrongful acts have proximately caused and will continue to cause Plaintiff substantial injury, including loss of customers, dilution of goodwill, confu-

sion of existing and potential customers, and diminution of the value of Plaintiff's products. The harm these wrongful acts will cause to Plaintiff is both imminent and irreparable, and the amount of damage sustained by Plaintiff will be difficult to ascertain if these acts continue. Plaintiff has no adequate remedy at law.

47. Plaintiff is entitled to an injunction restraining Defendants, their officers, agents, employees, and all persons acting in concert with them from engaging in further such unlawful conduct.

48. Plaintiff is further entitled to a restitutionary recovery from Defendants.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

1. For temporary, preliminary and permanent injunctive relief prohibiting Defendants, their agents, or anyone working for, in concert with or on behalf of Defendants from engaging in false or misleading advertising with respect to the their Pomegranate Blueberry Product and/or violating Lanham Act § 43(a), which relief includes but is not limited to removal of all false or misleading advertisements and corrective advertising to remedy the effects of Defendants' false advertising.

2. For an order requiring Defendants to correct any erroneous impression persons may have derived concerning the nature, characteristics, or qualities of their Pomegranate Blueberry Products, including without limitation, the placement of corrective advertising and providing written notice to the public.

3. That Defendants be adjudged to have violated 15 U.S.C. §1125(a) by unfairly competing against Plain-

tiff by using false, deceptive or misleading statements of fact that misrepresent the nature, quality and characteristics of their Pomegranate Blueberry Products.

4. That Defendants be adjudged to have unlawfully and unfairly competed against Plaintiff under the laws of the State of California, Cal. Bus. & Prof. Code §17200, *et seq.*

5. That Defendants be adjudged to have unfairly competed against Plaintiff by engaging in false or misleading advertising under the laws of the State of California, Cal. Bus. & Prof. Code §17500, *et seq.*

6. That Plaintiff be awarded damages Plaintiff has sustained in consequence of Defendants' conduct.

7. That Plaintiff be awarded Defendants' profits obtained by Defendant as a consequence of Defendants' conduct.

8. That such damages and profits be trebled and awarded to Plaintiff as a result of Defendants' willful, intentional and deliberate acts in Plaintiff violation of Lanham Act § 43(a).

9. That Plaintiff recover its costs and reasonable attorneys' fees.

10. That all of Defendants' misleading and deceptive materials and products be destroyed as allowed under 15 U.S.C. §1118.

11. That Plaintiffs be granted prejudgment and post judgment interest.

12. That Plaintiff have such other and further relief as the Court deems just and proper.

Dated: September 22, 2008 LOEB & LOEB LLP
ANDREW S. CLARE

MARK D. CAMPBELL
DAVID GROSSMAN

By: /s/ Mark D. Campbell
Mark D. Campbell
Attorneys for Plaintiff
POM WONDERFUL LLC

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury on all issues properly triable by jury.

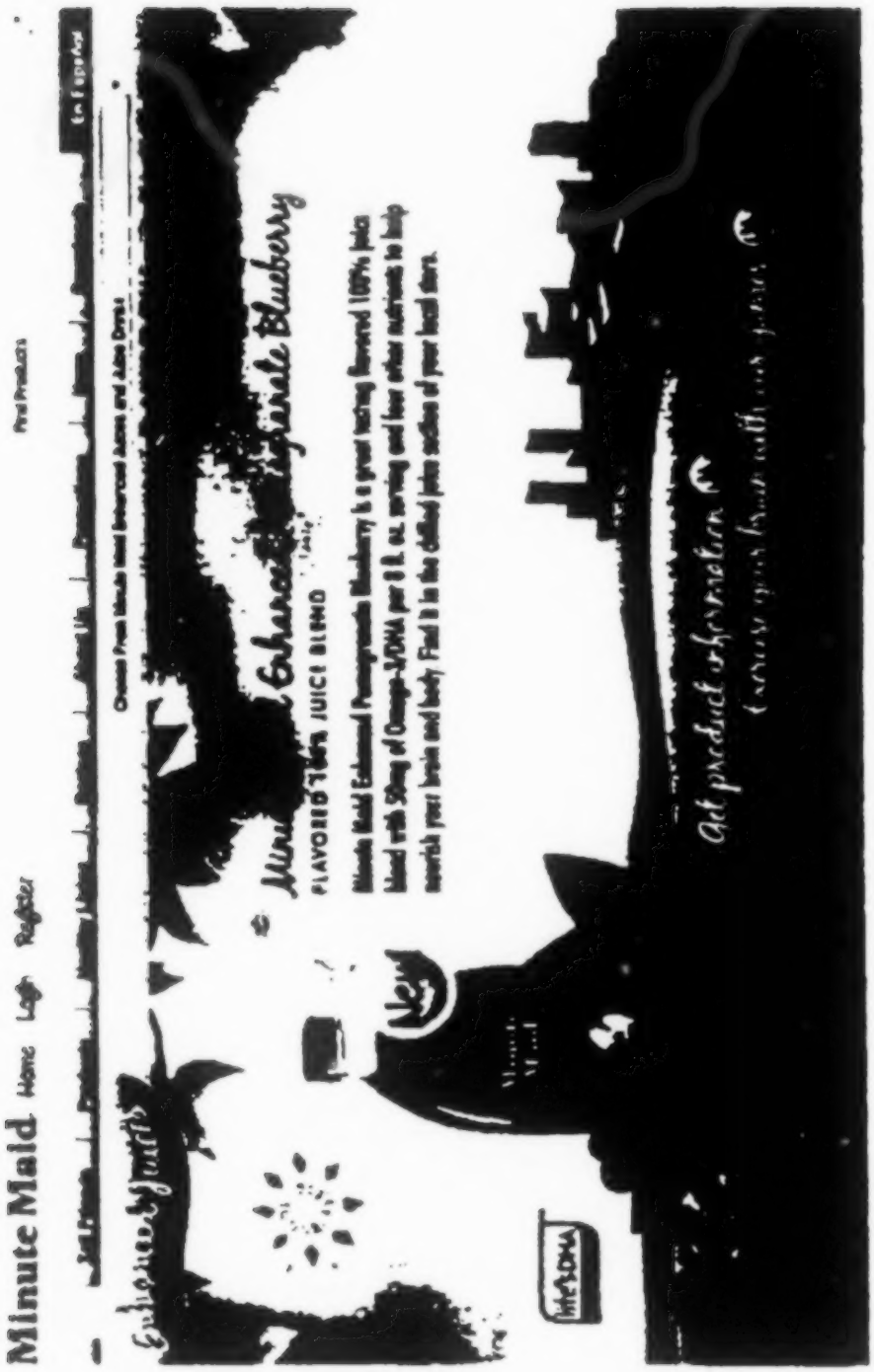
Dated: September 22, 2008

LOEB & LOEB LLP
ANDREW S. CLARE
MARK D. CAMPBELL
DAVID GROSSMAN

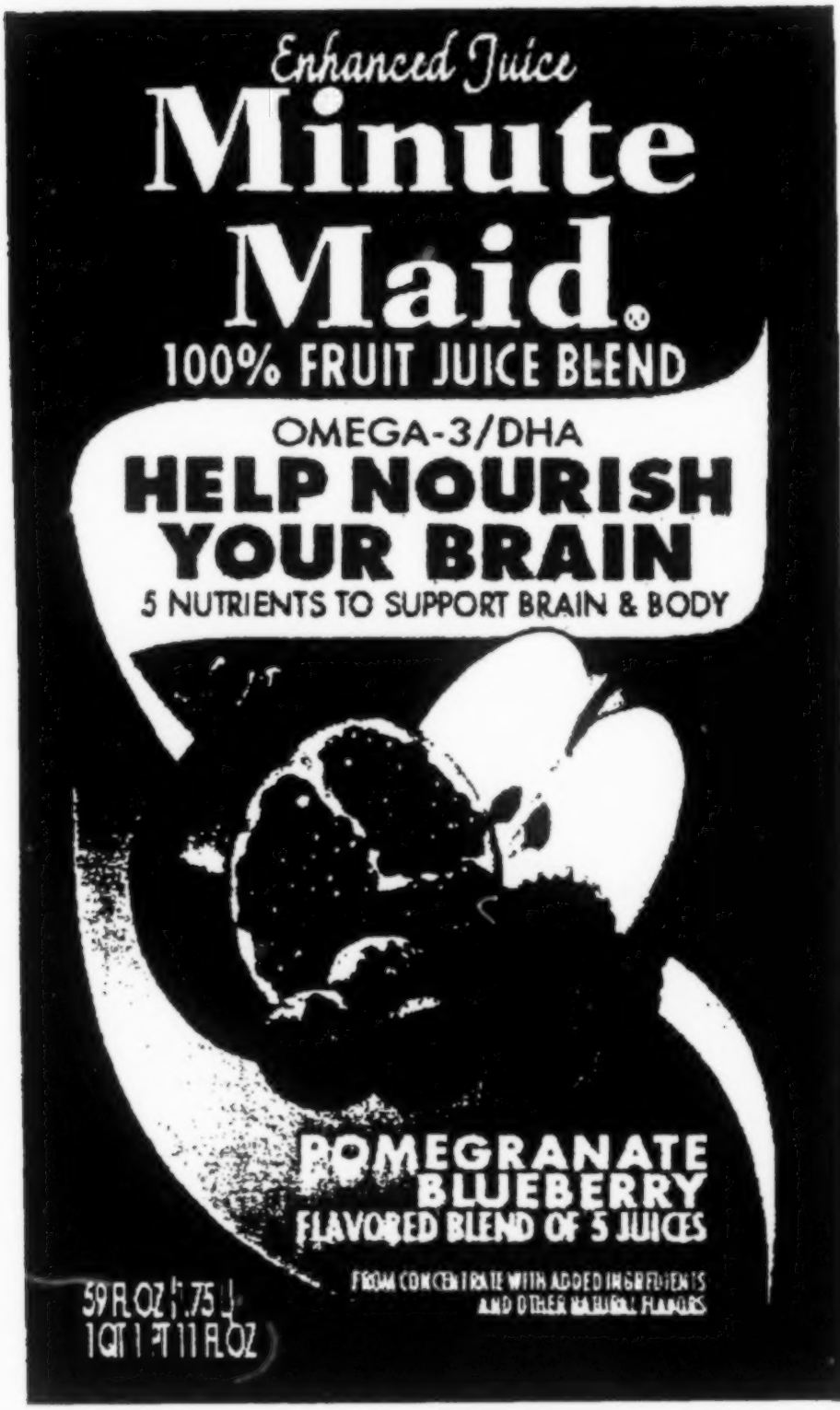
By: /s/ Mark D. Campbell
Mark D. Campbell
Attorneys for Plaintiff
POM WONDERFUL LLC

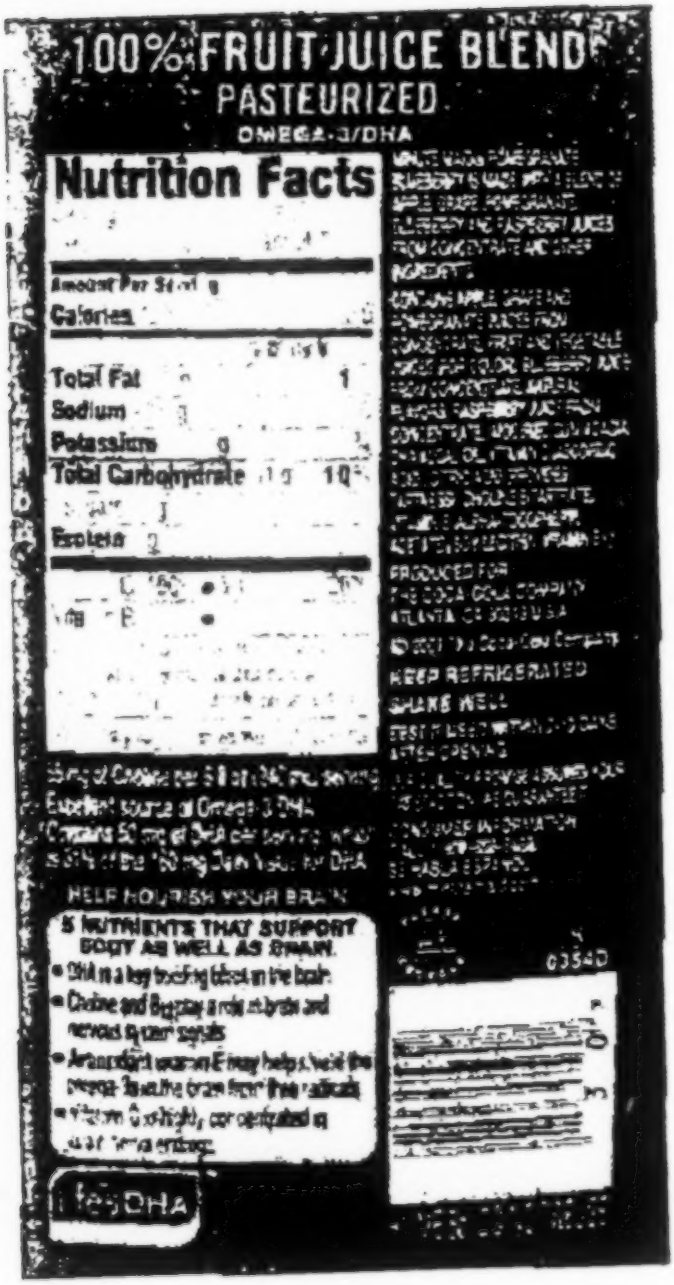
EXHIBIT A

EXHIBIT B


Minute Maid
Home
Login
Register
FLAVORED TEAS JUICE BLEND
Blended with 250mg of Omega-3/DHA per 8 fl. oz. serving and four other nutrients to help
nourish your brain and body. Find it in the chilled juice section of your local store.
DHA/OMEGA-3

Excerpt of Exhibit A to Declaration
of Kristin S. Escalante, Dist. Dkt. 9




100% FRUIT JUICE BLEND
PASTEURIZED
OMEGA-3/DHA
Nutrition Facts
Amount Per Serving
Calories
Total Fat
Sodium
Potassium
Total Carbohydrate
Protein
PRODUCED FOR
THE COCA-COLA COMPANY
ATLANTA GA 30313 U.S.A.
KEEP REFRIGERATED
SHAKE WELL
HELP NOURISH YOUR BRAIN
5 NUTRIENTS THAT SUPPORT
BODY AS WELL AS BRAIN.
DHA is a key building block in the brain.
Choline and Tryptophan a mix to brain and
nervous system signals
Antioxidant vitamin E may help shield the
precious fats in the brain from free radicals
Vitamin C (ascorbic), can contribute to
your immune system.
0354D

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

POM WONDERFUL LLC,
a Delaware limited liability company,
Plaintiff,

v.

THE COCA COLA COMPANY,
a Delaware corporation; and DOES 1-100,
Defendants.

CASE NO. CV08-06237 SJO (JTLx)
Judge: Honorable S. James Otero
March 2, 2009

DEFENDANT'S ANSWER TO COMPLAINT; DEMAND FOR JURY TRIAL

Defendant The Coca Cola Company ("TCCC"), by and through its counsel of record, hereby answers the Complaint ("Complaint") of Plaintiff POM Wonderful LLC ("POM") as follows:

RESPONSES TO PLAINTIFF'S ALLEGATIONS

1. Answering paragraph 1, TCCC lacks information sufficient to form a belief as to the state of incorporation and principal place of business of Plaintiff, and on that basis denies each and every allegation contained therein.

2. Answering paragraph 2, TCCC admits the allegations contained therein.

3. Answering paragraph 3, TCCC lacks information sufficient to form a belief as to the knowledge of the Plaintiff, or its intent to amend the Complaint, and on that basis denies the allegations.

4. TCCC denies each and every allegation contained in paragraph 4.

5. Answering paragraph 5, TCCC admits the allegations contained therein.

6. Answering paragraph 6, TCCC admits that the Court has jurisdiction over Plaintiff's complaint in this action.

7. Answering paragraph 7, TCCC admits that venue is proper in this Court.

8. TCCC denies each and every allegation in paragraph 8.

9. TCCC denies each and every allegation in paragraph 9.

10. Answering paragraph 10, TCCC lacks information sufficient to form a belief as to the size and nature of Plaintiff's business, and on that basis denies each and every allegation contained therein.

11. Answering paragraph 11, TCCC lacks information sufficient to form a belief as to Plaintiff's business, and on that basis denies each and every allegation contained therein.

12. Answering paragraph 12, TCCC lacks information sufficient to form a belief as to Plaintiff's business, and on that basis denies each and every allegation contained therein.

13. Answering paragraph 13, TCCC lacks information sufficient to form a belief as to what unidenti-

fied "scientists" referenced in paragraph 13 have "discovered" regarding pomegranate juice, and on that basis denies each and every allegation contained therein.

14. Answering paragraph 14, TCCC lacks information sufficient to form a belief as to the key elements of Plaintiff's marketing campaigns, and on that basis denies each and every allegation contained therein.

15. Answering paragraph 15, TCCC lacks information sufficient to form a belief as to the reasons for the growth of the pomegranate juice market, Plaintiff's position in that market in terms of geography or sales, or Plaintiff's revenues, and on that basis denies each and every allegation contained therein.

16. TCCC denies each and every allegation in paragraph 16.

17. Answering the first sentence of paragraph 17, TCCC admits that it sells bottled juice products under the brand name Minute Maid, and that it owns Odwalla, a company that also sells bottled juice products. TCCC denies that its Minute Maid Pomegranate Blueberry Flavored Blend of 5 Juices product is a primary competitor of Plaintiff in the "bottled pomegranate juice market." TCCC admits that Odwalla produces a pomegranate juice product that competes with Plaintiff's pomegranate juice. Except as expressly admitted, TCCC denies each and every allegation contained in the first sentence of paragraph 17. TCCC admits the allegations contained in the second sentence of paragraph 17.

18. Answering paragraph 18, TCCC admits that it introduced a product called Pomegranate Blueberry Flavored Blend of 5 Juices as part of its "Minute Maid Enhanced Juices" line of juices targeting consumers

interested in the health benefits of the DHA and Omega-3's that are added to the product. Except as expressly admitted, TCCC denies each and every allegation contained in the first sentence of paragraph 18. TCCC admits that the image displayed after paragraph 18 appears to be a photograph of the front of the bottle, including the front label, of its Pomegranate Blueberry Flavored Blend of 5 Juices product.

19. Answering the first sentence of paragraph 19, TCCC lacks information sufficient to form a belief as to the allegation that the blueberry has become a staple for health conscious consumers, and on that basis denies each and every allegation contained therein. TCCC denies each and every allegation in the second sentence of paragraph 19. Answering the third sentence of paragraph 19, TCCC admits, as the label itself states, that the first and second juices by volume in the Pomegranate Blueberry Flavored Blend of 5 Juices product are apple and grape juice.

20. Answering the first sentence of paragraph 20, TCCC admits that pomegranate and blueberry are, as listed in the ingredients panel, the third and fifth ingredients by volume in the product. TCCC denies that the name of its product is "Pomegranate Blueberry" juice. Answering the second sentence of paragraph 20, TCCC admits that the images attached as Exhibit A to the Complaint appear to be photographs of its Pomegranate Blueberry Flavored Blend of 5 Juices product. TCCC again denies that the name of its product is "Pomegranate Blueberry." Answering the third sentence of paragraph 20, TCCC admits that it maintains a website on which Minute Maid products are identified, including the Minute Maid Enhanced Juices. TCCC denies that its Pomegranate Blueberry Flavored Blend of 5 Juices is prominently advertised or marketed on

the website, or that the product is identified on the website as "Minute Maid Enhanced Pomegranate Blueberry juice." Answering the fourth sentence of paragraph 20, TCCC denies that Exhibit B is a true and correct copy of its website. TCCC admits that Exhibit B is an image of one page on its website that identifies the Pomegranate Blueberry Flavored Blend of 5 Juices product. Except as expressly admitted, TCCC denies each and every allegation in paragraph 20.

21. Answering paragraph 21, TCCC admits that it has advertised its Minute Maid Enhanced Juices, including the Pomegranate Blueberry Flavored Blend of 5 Juices product. Except as expressly admitted, TCCC denies each and every allegation in paragraph 21.

22. TCCC denies each and every allegation contained in the first and second sentences of paragraph 22. TCCC admits the allegations contained in the third and fourth sentences of paragraph 22, other than the name of the product, which TCCC denies is "Pomegranate Blueberry."

23. TCCC denies each and every allegation in paragraph 23.

24. TCCC denies each and every allegation in paragraph 24.

25. TCCC denies each and every allegation in paragraph 25.

26. TCCC denies each and every allegation in paragraph 26.

27. Answering paragraph 27, TCCC repeats its responses to paragraphs 1 through 27 as though set forth here in full.

28. TCCC denies each and every allegation in paragraph 28.

29. TCCC denies each and every allegation in paragraph 29.

30. TCCC denies each and every allegation in paragraph 30.

31. TCCC denies each and every allegation in paragraph 31.

32. TCCC denies each and every allegation in paragraph 32.

33. TCCC denies each and every allegation in paragraph 33.

34. TCCC denies each and every allegation in paragraph 34.

35. TCCC denies each and every allegation in paragraph 35.

36. Answering paragraph 36, TCCC repeats its responses to paragraphs 1 through 35 as though set forth here in full.

37. TCCC denies each and every allegation in paragraph 37.

38. TCCC denies each and every allegation in paragraph 38.

39. TCCC denies each and every allegation in paragraph 39.

40. TCCC denies each and every allegation in paragraph 40.

41. TCCC denies each and every allegation in paragraph 41.

42. Answering paragraph 42, TCCC repeats its responses to paragraphs 1 through 41 as though set forth here in full.

43. TCCC denies each and every allegation in paragraph 43

44. TCCC denies each and every allegation in paragraph 44.

45. TCCC denies each and every allegation in paragraph 45.

46. TCCC denies each and every allegation in paragraph 46.

47. TCCC denies each and every allegation in paragraph 47.

48. TCCC denies each and every allegation in paragraph 48.

AFFIRMATIVE DEFENSES

TCCC sets forth below its affirmative defenses. By setting forth these affirmative defenses, TCCC does not assume the burden of proving any fact, issue, or element of a cause of action where such burden properly belongs to Plaintiff. Moreover, nothing stated herein is intended or shall be construed as an acknowledgement that any particular issue or subject matter necessarily is relevant to Plaintiff's allegations.

FIRST AFFIRMATIVE DEFENSE

(Failure To State A Cause Of Action)

Each cause of action in the Complaint fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

(Equitable Defenses)

Plaintiff's claims against TCCC are barred, in whole or in part, by the doctrines of laches, unclean hands and waiver.

THIRD AFFIRMATIVE DEFENSE

(First Amendment Rights)

The Complaint, and each cause of action therein, is barred to the extent that the conduct complained of is protected by the free speech provisions of the California and United States constitutions.

FOURTH AFFIRMATIVE DEFENSE

(Good Faith)

Each cause of action is barred, in whole or in part, because TCCC acted in good faith at all times.

FIFTH AFFIRMATIVE DEFENSE

(Lack of Intent)

Plaintiff's claims based on alleged willful misrepresentations are barred because the representations and actions alleged were not intended to mislead or deceive consumers.

SIXTH AFFIRMATIVE DEFENSE

(Puffing)

Plaintiff's claims for false advertising are barred because the alleged deceptive statements were such that no reasonable person could have reasonably relied upon or misunderstood TCCC's statements as claims of fact.

SEVENTH AFFIRMATIVE DEFENSE

(Unconstitutionality Of Monetary Relief)

An award of monetary relief, other than restitution, to Claimant under California's Business & Professions Code Sections 17200 and 17500, including but not limited to penalties of any type, would violate the due process provisions of the United States and California constitutions.

EIGHTH AFFIRMATIVE DEFENSE

(Causation Is Lacking)

Each cause of action is barred, in whole or in part, because Plaintiff has not sustained any injury or damage by reason of any act or omission on TCCC's part.

NINTH AFFIRMATIVE DEFENSE

(Materiality Is Lacking)

Each cause of action is barred, in whole or in part, because Plaintiff has not sustained any injury or damage by reason of any material act or omission on TCCC's part.

TENTH AFFIRMATIVE DEFENSE

(Lack of Reliance)

Plaintiff's claims are barred, in whole or in part, because of the lack of reliance by consumers on the alleged misrepresentations by TCCC identified in the Complaint.

ELEVENTH AFFIRMATIVE DEFENSE

(Lack of Awareness)

Plaintiffs' claims are barred, in whole or in part, because consumers lacked awareness of the alleged misrepresentations by TCCC described in the Complaint.

TWELFTH AFFIRMATIVE DEFENSE

(Conduct Not Unlawful)

The business practices relating to the allegations in the Claim are not unlawful.

THIRTEENTH AFFIRMATIVE DEFENSE

(Conduct Not Fraudulent Nor Likely To Deceive)

TCCC's conduct is not fraudulent and was not likely to mislead or deceive consumers and/or the public.

FOURTEENTH AFFIRMATIVE DEFENSE

(Lack of Materiality)

Plaintiff's claims based on alleged misrepresentations are barred because the representations alleged by Plaintiff were not material in that, in light of information commonly known to consumers, they were not likely to affect their purchasing decisions. TCCC's representations and actions alleged in the Complaint were not likely to mislead consumers acting reasonably under the circumstances.

FIFTEENTH AFFIRMATIVE DEFENSE

(Lack of Standing)

Plaintiff lacks either standing and/or capacity to bring some or all of the claims alleged in the Complaint.

SIXTEENTH AFFIRMATIVE DEFENSE

(Negligence and Misconduct of Others)

If there was any negligence or other misconduct proximately causing the damages allegedly sustained by Plaintiff, such negligence or misconduct was that of parties other than TCCC, and recovery should be barred or eliminated to that extent.

SEVENTEENTH AFFIRMATIVE DEFENSE

(Adequate Remedy at Law)

Plaintiff's claims for equitable relief are barred to the extent there is an adequate remedy at law.

EIGHTEENTH AFFIRMATIVE DEFENSE

(No Right to Injunctive Relief)

To the extent the Complaint seeks injunctive relief, Plaintiff is not entitled to such relief because the hardship that would be imposed on TCCC by any such relief would be greatly disproportionate to any hardship that Plaintiff might suffer in its absence. Further, any injunctive relief that would require regulation by the Court on an ongoing basis is inappropriate, and TCCC's advertising and marketing activities are already monitored by various federal and state agencies.

NINETEENTH AFFIRMATIVE DEFENSE

(No Right to Punitive or Exemplary Damages)

Plaintiff is not entitled to punitive or exemplary damages on any cause of action alleged in the Complaint. Any award of punitive or exemplary damages would violate the due process and/or equal protection clauses of the California and United States constitutions.

TWENTIETH AFFIRMATIVE DEFENSE

(No Right to Restitution)

While denying that Plaintiff has stated a valid claim or claims under California Business & Professions Code Sections 17200 and 17500, if such claims are found to exist, an order for restitution is barred to the extent that Plaintiff did not pay monies directly to TCCC. *See, e.g.*, Korea Supply Co. v. Lockheed Martin Corp., 29 Cal. 4th 1134 (2003).

TWENTY-FIRST AFFIRMATIVE DEFENSE

(No Attorneys' Fees)

Plaintiff's request for attorneys' fees in this matter is barred because it lacks any basis in law or contract.

TWENTY-SECOND AFFIRMATIVE DEFENSE

(Unjust Enrichment)

Plaintiff's claims are barred to the extent Plaintiff would be unjustly enriched if allowed to recover any monies claimed to be due in the Complaint.

TWENTY-THIRD AFFIRMATIVE DEFENSE

(Damages Caused By Other Causes)

To the extent that Plaintiff suffered any damages, such damages were proximately caused by persons, entities, and/or factors or events other than TCCC and for which TCCC was and is not responsible.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

(Failure to Mitigate)

Without admitting any wrongful conduct on the part of TCCC, and without admitting that Plaintiff has

suffered any loss, damage or injury, recovery for any such loss, damage, or injury is barred, in whole or in part, because Plaintiff failed to mitigate such loss, damage, or injury.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

(Lack of Damage)

Plaintiff has not suffered any damage as a result of any actions allegedly taken by TCCC, and are thus barred from asserting any claim against TCCC.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

(Justification/Excuse)

TCCC's alleged actions, at all relevant times and places, were necessary to the competitive operation of its business, and Plaintiff's alleged injury, if any, is outweighed by the benefit to the public of TCCC's actions.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

(Statute of Limitations)

Plaintiff's claims are barred by the applicable statutes of limitations.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

(Set-off)

TCCC alleges that, even if Plaintiff's claims are meritorious, which TCCC denies, those claims are subject to setoff and recoupment

TWENTY-NINTH AFFIRMATIVE DEFENSE

(Federal Preemption)

Plaintiff's claims are expressly and impliedly preempted by federal law, including but not limited to, the Food, Drug and Cosmetic Act.

THIRTIETH AFFIRMATIVE DEFENSE

(Safe Harbor)

Plaintiff's state law claims are barred by California's safe harbor doctrine because TCCC's alleged actions, at all relevant times and places, were in compliance with applicable law.

THIRTY-FIRST AFFIRMATIVE DEFENSE

(Primary/ Exclusive Jurisdiction)

Plaintiff's claims are barred by the doctrines of primary and/or exclusive regulatory agency jurisdiction.

THIRTY-SECOND AFFIRMATIVE DEFENSE

(Compliance with Laws)

Plaintiff's claims are barred because the conduct alleged in the Complaint complies with applicable laws, including but not limited to Food and Drug Administration regulations and the Food, Drug, and Cosmetic Act.

THIRTY-THIRD AFFIRMATIVE DEFENSE

(Uncertain/ Unmangeable Damages)

Plaintiffs' requested monetary relief is too speculative and/or remote and/or impossible to prove and/or allocate.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

(Reservation)

Further responding, TCCC states that it currently has insufficient knowledge or information on which to form a belief as to whether it may have additional, as yet unstated, affirmative defenses available. TCCC reserves the right to assert additional affirmative defenses in the event that discovery indicates it would be appropriate.

PRAYER

WHEREFORE, TCCC prays for judgment as follows:

1. That Plaintiff takes nothing by way of the Complaint;

2. That the Complaint be dismissed with prejudice and judgment entered in favor of TCCC.

3. That TCCC be awarded its costs, disbursements and attorneys' fees in this action; and

4. For such other and further relief as this Court deems just and proper.

DATED: March 2, 2009

MUNGER, TOLLES & OLSON LLP
MARC T.G. DWORSKY
GREGORY D. PHILLIPS
MARTIN D. BERN
ALISON J. MARKOVITZ

By: */s/ Martin D. Bern*
MARTIN D. BERN
Attorneys for Defendant
The Coca-Cola Company

DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. 38(b), Defendant demands a trial by jury of all triable issues and affirmative defenses herein.

DATED: March 2, 2009 MUNGER, TOLLES & OLSON LLP
MARC T.G. DWORSKY
GREGORY D. PHILLIPS
MARTIN D. BERN
ALISON J. MARKOVITZ

By: */s/ Martin D. Bern*
MARTIN D. BERN
Attorneys for Defendant
The Coca-Cola Company

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

POM WONDERFUL LLC,
a Delaware limited liability company,
Plaintiff,

v.

THE COCA COLA COMPANY,
a Delaware corporation; and DOES 1-10, inclusive,
Defendants.

Case No. CV-08-06237 SJO (JTLx)
July 27, 2009

FIRST AMENDED COMPLAINT FOR FALSE ADVERTISING UNDER LANHAM ACT § 43(A); FALSE ADVERTISING UNDER CALIFORNIA BUSINESS & PROFESSIONS CODE § 17500, ET SEQ.; UNFAIR COMPETITION UNDER CALIFORNIA BUSINESS & PROFESSIONS CODE § 17500, ET SEQ.

DEMAND FOR JURY TRIAL

Plaintiff POM WONDERFUL LLC ("Pom Wonderful" or "Plaintiff") hereby alleges as follows:

PARTIES

1. Plaintiff Pom Wonderful is a Delaware limited liability company with its principal place of business in Los Angeles, California.

2. On information and belief, defendant The Coca Cola Company ("Coca Cola") is a Delaware corporation with its principal place of business in Atlanta, Georgia.

3. Plaintiff is not aware of the true names and capacities of the defendants identified herein as Does 1 through 10, inclusive, and therefore fictitiously names said defendants. Plaintiff will amend this Complaint to allege the true names and capacities of these fictitiously named defendants when their identities are ascertained.

4. Plaintiff is informed and believes, and thereon alleges, that Coca Cola and each of the fictitiously named Doe defendants (collectively "Defendants") were in some manner responsible for the acts alleged herein and the harm, losses and damages suffered by Plaintiff as alleged hereinafter. Plaintiff is also informed and believes that, while participating in such acts, each Defendant was the agent, alter ego, conspirator, and aidor and abettor of the other Defendants and was acting in the course and scope of such agency and/or acted with the permission, consent, authorization or ratification of the other Defendants.

5. As described further below, Coca Cola conducts business and manufactures and/or distributes products in the greater Los Angeles area, and throughout the United States.

JURISDICTION AND VENUE

6. This action arises under 15 U.S.C. § 1125(a) and the statutory law of the State of California. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §1331 (federal question), 15 U.S.C. § 1121 (Lanham Act claims) and 28 U.S.C. §1367 (supplemental jurisdiction).

7. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and 1400 because a substantial part of

the events or omissions giving rise to the claims occurred in this District.

FACTUAL ALLEGATIONS COMMON TO ALL CLAIMS

8. This action seeks redress for Coca Cola's deliberate and unlawful false and misleading representations regarding its Minute Maid Enhanced Pomegranate Blueberry product ("Pomegranate Blueberry Product"), which has been packaged, marketed and sold by Coca Cola based on the representation that the primary ingredients in the product are pomegranate and blueberry juice, when, in fact, the primary ingredients are actually apple and grape juice.

9. This action also seeks redress for the unfair, unlawful and fraudulent business practices of all Defendants, each of whom have participated in making the false advertising claims relating to Coca Cola's Pomegranate Blueberry Product in California and nationwide.

I. POM WONDERFUL

10. Plaintiff is the largest grower and distributor of pomegranates and pomegranate juice in the United States.

11. Plaintiff produces, markets and sells POM WONDERFUL® brand bottled pomegranate juice, and various pomegranate juice blends including a pomegranate blueberry blend. Pom Wonderful has been bottling, selling and marketing its juice products since 2002.

12. When Pom Wonderful began the development and distribution of POM WONDERFUL® juice, it invested millions of dollars in researching the nutritional

qualities and health benefits of pomegranate juice, an investment that continues to this day. Pom Wonderful has consulted with world-renowned scientists, including a Nobel laureate, and underwrites major research studies, many of which are published in well-known and prestigious peer-reviewed scientific and medical journals.

13. Scientists have discovered that pomegranate juice has very high levels of unique polyphenols, antioxidants that are particularly effective at neutralizing free radicals, preventing oxidation of LDL cholesterol (the "bad" cholesterol) and plaque build-up in the blood vessels, and preserving nitric oxide, a key chemical in the body for regulating blood flow and maintaining vessel health.

14. A key element of Pom Wonderful's marketing campaign has been its concentration on the health benefits associated with pomegranates and pomegranate juice, and its emphasis on the high level of antioxidants contained in POM WONDERFUL® brand juice.

15. Through its investment of millions of dollars to research and promote the nutritional qualities and health benefits associated with pomegranate juice, Plaintiff largely created the burgeoning market for genuine pomegranate juice that exists today. POM Wonderful's pomegranate juice has, in only six short years, eclipsed all other products in its market segment of super premium juices to take the #1 spot nationwide in supermarket sales, as well as the #l spots in the key geographic regions of Los Angeles, Chicago, New York, among many others. POM Wonderful's annual supermarket sales have, incredibly, gone from zero to well over $70 million in that same period.

16. Due to POM's marketing efforts and funding of research, and substantial research not funded by POM, many consumers now associate pomegranate juice with certain nutritional qualities and health benefits. Unscrupulous competitors have set out to cash in on Plaintiffs success by marketing and selling to consumers products labeled as "pomegranate juice," that in fact contain little or no actual pomegranate juice. Coca Cola is one such competitor.

II. COCA COLA AND ITS FALSE ADVERTISING OF ITS POMEGRANATE BLUEBERRY PRODUCT

17. Coca Cola markets and sells various bottled juice products under such brands as, among others, Odwalla and Minute Maid, and is currently one of Plaintiff's primary competitors in the bottled pomegranate juice market. Coca Cola is based in Atlanta, Georgia and, Plaintiff is informed and believes, markets, distributes and sells its products, including its Pomegranate Blueberry Product, in Los Angeles County and throughout the United States.

18. In September 2007, Coca Cola announced the addition of a new "Minute Maid® Pomegranate Blueberry" product to its line of "Minute Maid Enhanced Juices" targeting "the health-conscious shopper."

19. Like the pomegranate, in recent years the blueberry has become a staple for health conscious consumers because of its high antioxidant capacity. Thus, Coca Cola's Pomegranate Blueberry Product purports to combine two of nature's most powerful antioxidants into a single "Enhanced Juice" product. In fact, the main ingredients in Coca Cola's Pomegranate Blueberry Product are neither pomegranate nor blueberry juice, but rather, apple and grape juice.

20. Notwithstanding that Coca Cola's product actually contains little pomegranate or blueberry juice, Coca Cola decided to create a label with many misleading elements not required by federal or state regulation. For example, instead of calling its product "Apple Grape" juice, which are the two primary juices in its product, Coca Cola made a marketing decision to give this product the brand name of "Pomegranate Blueberry" juice on the front label, and to juxtapose this brand name with a picture of a pomegranate and other fruits, among other misleading elements. Attached as "Exhibit A" are true and correct copies of photographs of Coca Cola's Pomegranate Blueberry Product.

21. In addition to the claims on the product itself, Coca Cola also maintains a website at <minute-

maid.com> that prominently advertises and markets Coca Cola's product as "Minute Maid Enhanced Pomegranate Blueberry" juice. Attached as "Exhibit B" is a true and correct copy of Coca Cola's website advertising its Pomegranate Blueberry Product.

22. Coca Cola has also advertised its Pomegranate Blueberry Product in commercial spots aired during highly rated television shows such as American Idol. Plaintiff is informed and believes that Coca Cola has engaged in other forms of marketing and advertising of its Pomegranate Blueberry Product targeting consumers throughout the United States.

23. Purchasers of Coca Cola's product are likely to be misled and deceived by Coca Cola's product labeling, marketing and advertising. By name alone, one would expect that the primary ingredients in Coca Cola's Pomegranate Blueberry Product are pomegranate and blueberry juice. However, pomegranate juice ranks third, by volume, behind apple and grape juice in Coca Cola's Pomegranate Blueberry Product. Blueberry juice is found in even smaller amounts, ranking fifth among the ingredients found in Coca Cola's product.

24. Coca Cola's false and misleading advertising of its Pomegranate Blueberry Product is damaging to the reputation and goodwill of Plaintiff and is damaging to the consuming public. These false and misleading representations are designed to entice consumers to purchase Coca Cola's product over Plaintiffs products. Specifically, Coca Cola's false and misleading representations regarding the primary ingredients of its product deceive consumers, causing them to believe that its product, like Plaintiff's product, primarily contains pomegranate and blueberry juice. The truth is that Coca Cola's product primarily contains apple juice and

grape juice, which are much less expensive juices than pomegranate juice and blueberry juice.

25. Because the cost to produce Coca Cola's product is far less than the cost to produce actual pomegranate blueberry juice (*i.e.*, a juice product whose primary ingredients are actually pomegranate and blueberry juice), Coca Cola can charge less for its product than competitors, including Plaintiff, while reaping a substantial profit. In this way, Coca Cola entices consumers who would otherwise buy Plaintiff's product to buy its product instead. In doing so, Coca Cola wrongfully misleads and deceives consumers, and tricks them into believing that they are getting a similar product (*i.e.*, all natural pomegranate blueberry juice with all of its associated health benefits) for a lower price, when in fact they are getting a very different product primarily containing apple juice and grape juice.

26. The natural, probable and foreseeable result of Coca Cola's wrongful conduct has been to cause confusion, deception and mistake in the pomegranate blueberry juice market as a whole, to deprive Plaintiff of business and goodwill, and to injure Plaintiff's relationships with existing and prospective customers.

27. Plaintiff is informed and believes that Coca Cola's wrongful conduct has resulted in increased sales of Coca Cola's own Pomegranate Blueberry Product while hindering the sales of Plaintiff's pomegranate juice products and damaging Plaintiff's goodwill. Plaintiff has sustained and will sustain damages as a result of Coca Cola's wrongful conduct.

FIRST CLAIM FOR RELIEF

(False Advertising Under Lanham Act§ 43(a), 15 U.S.C. 1125(a) Against All Defendants)

28. Plaintiff incorporates by reference Paragraphs 1 through 27 above as though fully set forth herein.

29. Upon information and belief Defendants have made and distributed, in interstate commerce and in this District, advertisements that contain false or misleading statements of fact regarding their products. These advertisements contain actual misstatements and/or misleading statements and failures to disclose, including, among others, the statement that Defendants' product consists primarily of pomegranate and blueberry juice.

30. Upon information and belief, these false statements actually deceive, or have a tendency to deceive, a substantial segment of Plaintiffs customers and potential customers. This deception is material in that it is likely to influence the purchasing decisions of Plaintiff's customers.

31. Defendants' false and misleading advertising statements and omissions injure both consumers and Plaintiff.

32. Defendants' false and misleading advertising statements and omissions violate the Lanham Act§ 43(a), 15 U.S.C. §1125(a).

33. Defendants have caused, and will continue to cause, immediate and irreparable injury to Plaintiff, including injury to its business, reputation, and goodwill, for which there is no adequate remedy at law. As such, Plaintiff is entitled to an injunction under 15 U.S.C. §111 restraining Defendants, their agents, employees, representatives and all persons acting in concert with them from engaging in further acts of false advertising, and ordering removal of all Defendants' false advertisements.

34. Pursuant to 15 U.S.C. §1117, Plaintiff is entitled to recover from Defendants the damages sustained by Plaintiff as a result of Defendants' acts in violation of Lanham Act § 43(a). Plaintiff is at present unable to ascertain the full extent of the monetary damages it has suffered by reason of Defendants' acts.

35. Pursuant to 15 U.S.C. §1117, Plaintiff is further entitled to recover from Defendants the gains, profits and advantages that they have obtained as a result of their acts. Plaintiff is at present unable to ascertain the full amount of the gains, profits and advantages Defendants have obtained by reason of their acts.

36. Pursuant to 15 U.S.C. §1117, Plaintiff is further entitled to recover the costs of this action. Moreover, Plaintiff is informed and believes, and on that basis alleges, that Defendants' conduct was undertaken willfully and with the intention of causing confusion, mistake or deception, making this an exceptional case entitling Plaintiff to recover additional damages and reasonable attorneys' fees.

SECOND CLAIM FOR RELIEF

(False Advertising Under Cal. Bus. & Prof. Code § 17500 Against All Defendants)

37. Plaintiff incorporates by reference Paragraphs 1 through 36 above as though fully set forth herein.

38. Defendants knew or in the exercise of reasonable care should have known that their publicly disseminated statements and omissions relating to their Pomegranate Blueberry Product were false or misleading. Defendants' false advertising statements and omissions injure consumers and Plaintiff. Defendants' false and misleading statements include, among others, that De-

fendants' product consists primarily of pomegranate and blueberry juice.

39. By making such untrue or misleading statements, Defendants have engaged in false advertising in violation of the statutory law of the state of California, Cal. Bus. & Prof. Code §17500, *et seq.*

40. By reason of Defendants' conduct, Plaintiff has suffered injury in fact and has lost money or property.

41. Defendants have caused, and will continue to cause, immediate and irreparable injury to Plaintiff, including injury to its business, reputation, and goodwill, for which there is no adequate remedy at law. Plaintiff is entitled to an injunction restraining Defendants, their agents, employees, representatives and all persons acting in concert with them from engaging in further such acts, and forbidding Defendants from advertising their Pomegranate Blueberry Product as primarily containing pomegranate and blueberry juice, and from making other false statements in connection with the product.

42. Plaintiff is further entitled to a restitutionary recovery from Defendants

THIRD CLAIM FOR RELIEF

(Statutory Unfair Competition - Cal Bus. & Prof. Code §17200, *et seq.* Against All Defendants)

43. Plaintiff incorporates by reference Paragraphs 1 through 42 above as though fully set forth herein.

44. Defendants have made, published, disseminated, and circulated false, deceptive, and misleading statements, representations, and advertisements in California misrepresenting the nature, quality, and characteristics of their Pomegranate Blueberry Prod-

uct with the intent of selling, distributing, and increasing the consumption of, and interest in, their Pomegranate Blueberry Product.

45. Defendants' conduct as alleged herein constitutes unfair competition in that such acts were and are unlawful, unfair, deceptive and/or fraudulent business acts or practices in violation of California Business & Professions Code §17200, *et seq.*

46. Defendants' conduct as alleged herein constitutes unlawful, unfair, deceptive and/or fraudulent business acts or practices in violation of California Business & Professions Code §17200, *et seq.* because such acts were and are violations of California Health & Safety Code § 110660, which states: "Any food is misbranded if its labeling is false or misleading in any particular." Defendants have violated Section 110660 because the Pomegranate Blueberry Product's label misleads consumers into believing that it contains primarily pomegranate and blueberry juice.

47. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff has suffered injury in fact, which losses include damage to Plaintiff's good will with its existing, former and potential customers. Defendants' conduct has also caused damage to consumers.

48. These wrongful acts have proximately caused and will continue to cause Plaintiff substantial injury, including loss of customers, dilution of goodwill, confusion of existing and potential customers, and diminution of the value of Plaintiff's products. The harm these wrongful acts will cause to Plaintiff is both imminent and irreparable, and the amount of damage sustained by Plaintiff will be difficult to ascertain if these acts continue. Plaintiff has no adequate remedy at law.

49. Plaintiff is entitled to an injunction restraining Defendants, their officers, agents, employees, and all persons acting in concert with them from engaging in further such unlawful conduct.

50. Plaintiff is further entitled to a restitutionary recovery from Defendants.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against Defendants as follows:

1. For temporary, preliminary and permanent injunctive relief prohibiting Defendants, their agents, or anyone working for, in concert with or on behalf of Defendants from engaging in false or misleading advertising with respect to the their Pomegranate Blueberry Product and/or violating Lanham Act § 43(a), which relief includes but is not limited to removal of all false or misleading advertisements and corrective advertising to remedy the effects of Defendants' false advertising.

2. For an order requiring Defendants to correct any erroneous impression persons may have derived concerning the nature, characteristics, or qualities of their Pomegranate Blueberry Products, including without limitation, the placement of corrective advertising and providing written notice to the public.

3. That Defendants be adjudged to have violated 15 U.S.C. §1125(a) by unfairly competing against Plaintiff by using false, deceptive or misleading statements of fact that misrepresent the nature, quality and characteristics of their Pomegranate Blueberry Products.

4. That Defendants be adjudged to have unlawfully and unfairly competed against Plaintiff under the

laws of the State of California, Cal. Bus. & Prof. Code §17200, *et seq.*

5. That Defendants be adjudged to have unfairly competed against Plaintiff by engaging in false or misleading advertising under the laws of the State of California, Cal. Bus. & Prof. Code §17500, *et seq.*

6. That Plaintiff be awarded damages Plaintiff has sustained in consequence of Defendants' conduct.

7. That Plaintiff be awarded Defendants' profits obtained by Defendant as a consequence of Defendants' conduct.

8. That such damages and profits be trebled and awarded to Plaintiff as a result of Defendants' willful, intentional and deliberate acts in Plaintiff violation of Lanham Act § 43(a).

9. That Plaintiff recover its costs and reasonable attorneys' fees.

10. That all of Defendants' misleading and deceptive materials and products be destroyed as allowed under 15 U.S.C. §1118.

11. That Plaintiffs be granted prejudgment and post judgment interest.

12. That Plaintiff have such other and further relief as the Court deems just and proper.

Dated: July 27, 2009 ROLL INTERNATIONAL CORPORATION
LEGAL DEPARTMENT

By: /s/ Daniel S. Silverman
Daniel S. Silverman
Attorney for Plaintiff
POM WONDERFUL LLC

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury on all issues properly triable by jury.

Dated: July 27, 2009

ROLL INTERNATIONAL CORPORATION
LEGAL DEPARTMENT

By: /s/ Daniel S. Silverman
Daniel S. Silverman
Attorneys for Plaintiff
POM WONDERFUL LLC

EXHIBIT A

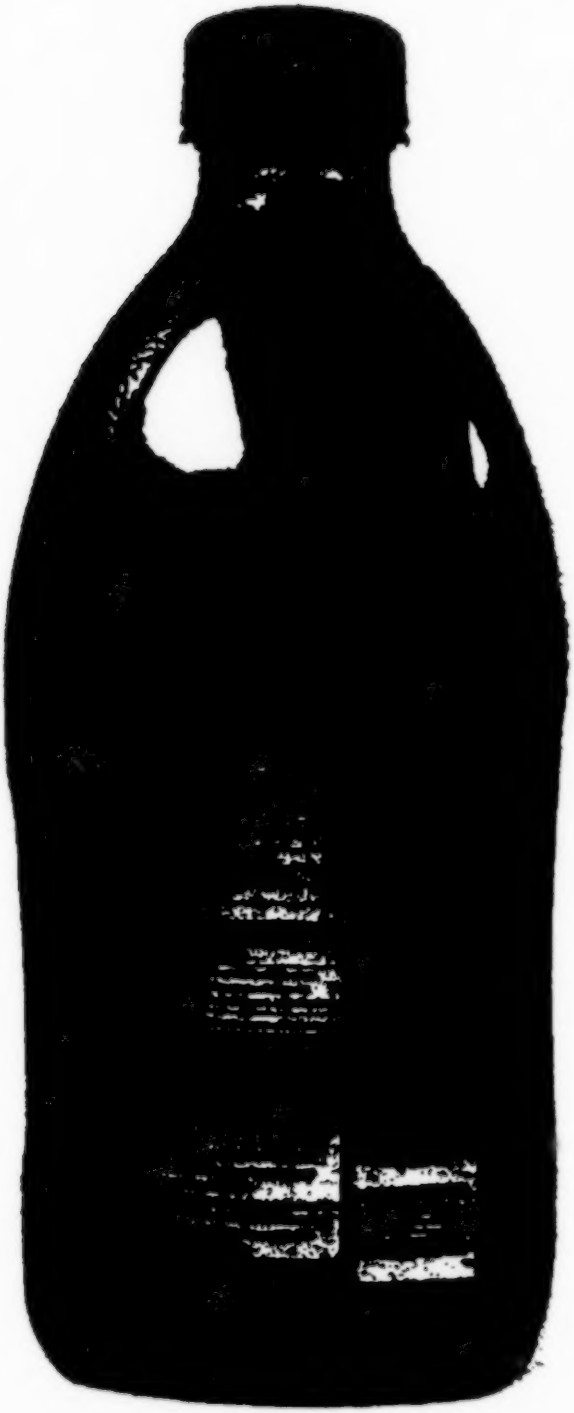


EXHIBIT B

Minute Maid
Home
Login
Register
Find Products...
Choose From Minute Maid Enhanced Juices and Juice Drinks
FLAVORED
Minute Maid Enhanced Pomegranate Blueberry is a great tasting flavored 100% juice blend with 50mg of Omega-3/DHA per 8 fl. oz. serving and four other nutrients to help nourish your brain and body. Find it in the chilled juice section of your local store.
New!
life's DHA

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

POM WONDERFUL LLC,
a Delaware limited liability company,
Plaintiff,

v.

THE COCA COLA COMPANY,
a Delaware corporation; and DOES 1-10,
Defendants.

CASE NO. CV08-06237 SJO (JTLx)
Judge: Honorable S. James Otero
September 30, 2009

DEFENDANT'S ANSWER TO FIRST AMENDED COMPLAINT; DEMAND FOR JURY TRIAL

Defendant The Coca Cola Company ("TCCC"), by and through its counsel of record, hereby answers the First Amended Complaint ("Complaint") of Plaintiff POM Wonderful LLC ("Plaintiff") as follows:

RESPONSES TO PLAINTIFF'S ALLEGATIONS

1. Answering paragraph 1, TCCC lacks information sufficient to form a belief as to the state of incorporation and principal place of business of Plaintiff, and on that basis denies each and every allegation contained therein.

2. Answering paragraph 2, TCCC admits the allegations contained therein.

3. Answering paragraph 3, TCCC lacks information sufficient to form a belief as to the knowledge of the Plaintiff, or its intent to amend the Complaint, and on that basis denies the allegations.

4. TCCC denies each and every allegation contained in paragraph 4.

5. Answering paragraph 5, TCCC admits the allegations contained therein.

6. Answering paragraph 6, TCCC admits that the Court has jurisdiction over Plaintiff's complaint in this action.

7. Answering paragraph 7, TCCC admits that venue is proper in this Court.

8. TCCC denies each and every allegation in paragraph 8.

9. TCCC denies each and every allegation in paragraph 9.

10. Answering paragraph 10, TCCC lacks information sufficient to form a belief as to the size and nature of Plaintiff's business, and on that basis denies each and every allegation contained therein.

11. Answering paragraph 11, TCCC lacks information sufficient to form a belief as to Plaintiff's business, and on that basis denies each and every allegation contained therein.

12. Answering paragraph 12, TCCC lacks information sufficient to form a belief as to Plaintiff's business, and on that basis denies each and every allegation contained therein.

13. Answering paragraph 13, TCCC lacks information sufficient to form a belief as to what unidenti-

fied "scientists" referenced in paragraph 13 have "discovered" regarding pomegranate juice, and on that basis denies each and every allegation contained therein.

14. Answering paragraph 14, TCCC lacks information sufficient to form a belief as to the key elements of Plaintiff's marketing campaigns, and on that basis denies each and every allegation contained therein.

15. Answering paragraph 15, TCCC lacks information sufficient to form a belief as to the reasons for the growth of the pomegranate juice market, Plaintiff's position in that market in terms of geography or sales, or Plaintiff's revenues, and on that basis denies each and every allegation contained therein.

16. Answering the first sentence of paragraph 16, TCCC lacks information sufficient to form a belief regarding Plaintiff's "marketing efforts" and "research," or whether "many consumers now associate pomegranate juice with certain nutritional qualities and health benefits," and on that basis denies each and every allegation contained therein. TCCC denies each and every allegation in the second sentence of paragraph 16.

17. Answering the first sentence of paragraph 17, TCCC admits that it sells bottled juice products under the brand name Minute Maid, and that it owns Odwalla, a company that also sells bottled juice products. TCCC denies that its Minute Maid Enhanced Juice Pomegranate Blueberry Flavored Blend of 5 Juices product (the "Juice") is a primary competitor of Plaintiff in the "bottled pomegranate juice market." TCCC admits that Odwalla produces a pomegranate juice product that competes with Plaintiff's pomegranate juice. Except as expressly admitted, TCCC denies each and every allegation contained in the first sentence of paragraph 17. TCCC admits the allegations contained in the second

sentence of paragraph 17, except that TCCC denies that the name of its product is "Pomegranate Blueberry" juice.

18. Answering paragraph 18, TCCC admits that it introduced the Juice as part of its "Minute Maid Enhanced Juices" line of juices for consumers interested in the health benefits of the DHA and Omega-3's that are added to the product. Except as expressly admitted, TCCC denies each and every allegation contained in the first sentence of paragraph 18. TCCC admits that the image displayed after paragraph 18 appears to be a photograph of the front of the bottle, including the front label, of the Juice.

19. Answering the first sentence of paragraph 19, TCCC lacks information sufficient to form a belief as to the allegation that the blueberry has become a staple for health conscious consumers, and on that basis denies each and every allegation contained therein. TCCC denies each and every allegation in the second sentence of paragraph 19. Answering the third sentence of paragraph 19, TCCC admits, as the label itself states, that the first and second juices by volume in the Juice are apple and grape juice.

20. Answering the first sentence of paragraph 20, TCCC admits that pomegranate and blueberry are, as listed in the ingredients panel, the third and fifth ingredients by volume in the Juice. Answering the second sentence of paragraph 20, TCCC admits that the first and second juices by volume in the Juice are apple and grape juice, as listed in the ingredients panel, and that the front label of the Juice contains a vignette of five fruits: apple, grape, pomegranate, blueberry, and raspberry. TCCC denies that the name of its product is "Pomegranate Blueberry" juice. Answering the third

sentence of paragraph 20, TCCC admits that the images attached as Exhibit A to the Complaint appear to be photographs of the Juice. TCCC again denies that the name of its product is "Pomegranate Blueberry." Except as expressly admitted, TCCC denies each and every allegation in paragraph 20.

21. Answering the first sentence of paragraph 21, TCCC admits that it maintains a website on which Minute Maid products are identified, including the Minute Maid Enhanced Juices. TCCC denies that the Juice is prominently advertised or marketed on the website, or that the product is identified on the website as "Minute Maid Enhanced Pomegranate Blueberry juice." Answering the second sentence of paragraph 21, TCCC denies that Exhibit B is a true and correct copy of its website. TCCC admits that Exhibit B is an image of one page on its website that identifies the Juice. Except as expressly admitted, TCCC denies each and every allegation in paragraph 21.

22. Answering paragraph 22, TCCC admits that it has advertised its Minute Maid Enhanced Juices, including the Juice. Except as expressly admitted, TCCC denies each and every allegation in paragraph 22.

23. TCCC denies each and every allegation contained in the first and second sentences of paragraph 23. TCCC admits the allegations contained in the third and fourth sentences of paragraph 23, other than the name of the product, which TCCC denies is "Pomegranate Blueberry."

24. TCCC denies each and every allegation in paragraph 24, except that TCCC admits that the first and second juices by volume in the Juice are apple and grape juice, as listed in the ingredients panel.

25. TCCC denies each and every allegation in paragraph 25.

26. TCCC denies each and every allegation in paragraph 26.

27. TCCC denies each and every allegation in paragraph 27.

28. Answering paragraph 28, TCCC repeats its responses to paragraphs 1 through 27 as though set forth here in full.

29. TCCC denies each and every allegation in paragraph 29.

30. TCCC denies each and every allegation in paragraph 30.

31. TCCC denies each and every allegation in paragraph 31.

32. TCCC denies each and every allegation in paragraph 32.

33. TCCC denies each and every allegation in paragraph 33.

34. TCCC denies each and every allegation in paragraph 34.

35. TCCC denies each and every allegation in paragraph 35.

36. TCCC denies each and every allegation in paragraph 36.

37. Answering paragraph 37, TCCC repeats its responses to paragraphs 1 through 36 as though set forth here in full.

38. TCCC denies each and every allegation in paragraph 38.

39. TCCC denies each and every allegation in paragraph 39.

40. TCCC denies each and every allegation in paragraph 40.

41. TCCC denies each and every allegation in paragraph 41.

42. TCCC denies each and every allegation in paragraph 42.

43. Answering paragraph 43, TCCC repeats its responses to paragraphs 1 through 42 as though set forth here in full.

44. TCCC denies each and every allegation in paragraph 44.

45. TCCC denies each and every allegation in paragraph 45.

46. TCCC denies each and every allegation in paragraph 46.

47. TCCC denies each and every allegation in paragraph 47.

48. TCCC denies each and every allegation in paragraph 48.

49. TCCC denies each and every allegation in paragraph 49.

50. TCCC denies each and every allegation in paragraph 50.

AFFIRMATIVE DEFENSES

TCCC sets forth below its affirmative defenses. By setting forth these affirmative defenses, TCCC does not assume the burden of proving any fact, issue, or element of a cause of action where such burden properly

belongs to Plaintiff. Moreover, nothing stated herein is intended or shall be construed as an acknowledgement that any particular issue or subject matter necessarily is relevant to Plaintiff's allegations.

FIRST AFFIRMATIVE DEFENSE

(Failure To State A Cause Of Action)

Each cause of action in the Complaint fails to state a claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

(Equitable Defenses)

Plaintiff's claims against TCCC are barred, in whole or in part, by the doctrines of laches, unclean hands and waiver.

THIRD AFFIRMATIVE DEFENSE

(First Amendment Rights)

The Complaint, and each cause of action therein, is barred to the extent that the conduct complained of is protected by the free speech provisions of the California and United States constitutions.

FOURTH AFFIRMATIVE DEFENSE

(Good Faith)

Each cause of action is barred, in whole or in part, because TCCC acted in good faith at all times.

FIFTH AFFIRMATIVE DEFENSE

(Lack of Intent)

Plaintiff's claims based on alleged willful misrepresentations are barred because the representations and

actions alleged were not intended to mislead or deceive consumers.

SIXTH AFFIRMATIVE DEFENSE

(Puffing)

Plaintiff's claims for false advertising are barred because the alleged deceptive statements were such that no reasonable person could have reasonably relied upon or misunderstood TCCC's statements as claims of fact.

SEVENTH AFFIRMATIVE DEFENSE

(Unconstitutionality Of Monetary Relief)

An award of monetary relief, other than restitution, to Claimant under California's Business & Professions Code Sections 17200 and 17500, including but not limited to penalties of any type, would violate the due process provisions of the United States and California constitutions.

EIGHTH AFFIRMATIVE DEFENSE

(Causation Is Lacking)

Each cause of action is barred, in whole or in part, because Plaintiff has not sustained any injury or damage by reason of any act or omission on TCCC's part.

NINTH AFFIRMATIVE DEFENSE

(Materiality Is Lacking)

Each cause of action is barred, in whole or in part, because Plaintiff has not sustained any injury or damage by reason of any material act or omission on TCCC's part.

TENTH AFFIRMATIVE DEFENSE

(Lack of Reliance)

Plaintiff's claims are barred, in whole or in part, because of the lack of reliance by consumers on the alleged misrepresentations by TCCC identified in the Complaint.

ELEVENTH AFFIRMATIVE DEFENSE

(Lack of Awareness)

Plaintiff's claims are barred, in whole or in part, because consumers lacked awareness of the alleged misrepresentations by TCCC described in the Complaint.

TWELFTH AFFIRMATIVE DEFENSE

(Conduct Not Unlawful)

The business practices relating to the allegations in the Claim are not unlawful.

THIRTEENTH AFFIRMATIVE DEFENSE

(Conduct Not Fraudulent Nor Likely To Deceive)

TCCC's conduct is not fraudulent and was not likely to mislead or deceive consumers and/or the public.

FOURTEENTH AFFIRMATIVE DEFENSE

(Lack of Materiality)

Plaintiff's claims based on alleged misrepresentations are barred because the representations alleged by Plaintiff were not material in that, in light of information commonly known to consumers, they were not likely to affect their purchasing decisions. TCCC's representations and actions alleged in the Complaint were

not likely to mislead consumers acting reasonably under the circumstances.

FIFTEENTH AFFIRMATIVE DEFENSE

(Lack of Standing)

Plaintiff lacks either standing and/or capacity to bring some or all of the claims alleged in the Complaint.

SIXTEENTH AFFIRMATIVE DEFENSE

(Negligence and/or Misconduct of Others)

If there was any negligence and/or other misconduct proximately causing the damages allegedly sustained by Plaintiff, such negligence and/or other misconduct was that of parties other than TCCC, and recovery should be barred or eliminated to that extent.

SEVENTEENTH AFFIRMATIVE DEFENSE

(Adequate Remedy at Law)

Plaintiff's claims for equitable relief are barred to the extent there is an adequate remedy at law.

EIGHTEENTH AFFIRMATIVE DEFENSE

(No Right to Injunctive Relief)

To the extent the Complaint seeks injunctive relief, Plaintiff is not entitled to such relief because the hardship that would be imposed on TCCC by any such relief would be greatly disproportionate to any hardship that Plaintiff might suffer in its absence. Further, any injunctive relief that would require regulation by the Court on an ongoing basis is inappropriate, and TCCC's advertising and marketing activities are already monitored by various federal and state agencies.

NINETEENTH AFFIRMATIVE DEFENSE

(No Right to Punitive or Exemplary Damages)

Plaintiff is not entitled to punitive or exemplary damages on any cause of action alleged in the Complaint. Any award of punitive or exemplary damages would violate the due process and/or equal protection clauses of the California and United States constitutions.

TWENTIETH AFFIRMATIVE DEFENSE

(No Right to Restitution)

While denying that Plaintiff has stated a valid claim or claims under California Business & Professions Code Sections 17200 and 17500, if such claims are found to exist, an order for restitution is barred to the extent that Plaintiff did not pay monies directly to TCCC. *See, e.g.*, Korea Supply Co. v. Lockheed Martin Corp., 29 Cal. 4th 1134 (2003).

TWENTY-FIRST AFFIRMATIVE DEFENSE

(No Attorneys' Fees)

Plaintiff's request for attorneys' fees in this matter is barred because it lacks any basis in law or contract.

TWENTY-SECOND AFFIRMATIVE DEFENSE

(Unjust Enrichment)

Plaintiff's claims are barred to the extent Plaintiff would be unjustly enriched if allowed to recover any monies claimed to be due in the Complaint.

TWENTY-THIRD AFFIRMATIVE DEFENSE

(Damages Caused By Other Causes)

To the extent that Plaintiff suffered any damages, such damages were proximately caused by persons, entities, and/or factors or events other than TCCC and for which TCCC was and is not responsible.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

(Failure to Mitigate)

Without admitting any wrongful conduct on the part of TCCC, and without admitting that Plaintiff has suffered any loss, damage or injury, recovery for any such loss, damage, or injury is barred, in whole or in part, because Plaintiff failed to mitigate such loss, damage, or injury.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

(Lack of Damage)

Plaintiff has not suffered any damage as a result of any actions allegedly taken by TCCC, and are thus barred from asserting any claim against TCCC.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

(Justification/Excuse)

TCCC's alleged actions, at all relevant times and places, were necessary to the competitive operation of its business, and Plaintiff's alleged injury, if any, is outweighed by the benefit to the public of TCCC's actions.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

(Statute of Limitations)

Plaintiff's claims are barred by the applicable statutes of limitations.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

(Set-off)

TCCC alleges that, even if Plaintiff's claims are meritorious, which TCCC denies, those claims are subject to setoff and recoupment

TWENTY-NINTH AFFIRMATIVE DEFENSE

(Federal Preemption)

Plaintiff's claims are expressly and impliedly preempted by federal law, including but not limited to, the Food, Drug and Cosmetic Act.

THIRTIETH AFFIRMATIVE DEFENSE

(Safe Harbor)

Plaintiff's state law claims are barred by California's safe harbor doctrine because TCCC's alleged actions, at all relevant times and places, were in compliance with applicable law.

THIRTY-FIRST AFFIRMATIVE DEFENSE

(Primary/ Exclusive Jurisdiction)

Plaintiff's claims are barred by the doctrines of primary and/or exclusive regulatory agency jurisdiction.

THIRTY-SECOND AFFIRMATIVE DEFENSE

(Compliance with Laws)

Plaintiff's claims are barred because the conduct alleged in the Complaint complies with applicable laws, including but not limited to Food and Drug Administration regulations and the Food, Drug, and Cosmetic Act.

THIRTY-THIRD AFFIRMATIVE DEFENSE

(Uncertain/ Unmangeable Damages)

Plaintiff's requested monetary relief is too speculative and/or remote and/or impossible to prove and/or allocate.

THIRTY-FOURTH AFFIRMATIVE DEFENSE

(Unclean Hands)

Plaintiff's claims against TCCC are barred, in whole or in part, due to unclean hands. Plaintiff has engaged in naming, labeling, marketing and advertising conduct designed to deceive consumers about its products. For instance, Plaintiff describes its Pomegranate Blueberry juice product as Pomegranate Blueberry 100% Juice, yet at the time it filed its Complaint, Plaintiff's product contained other ingredients, including plum, pineapple, apple, and blackberry juices from concentrates and natural flavors. In addition, Plaintiff's name, label, advertisements, website, and promotions of Plaintiff's pomegranate juice products—including its 100% pomegranate juice product and its 100% juice blend products, such as its Pomegranate Blueberry 100% Juice product—are designed to give consumers the false impression that these juices are fresh-squeezed, and not "from concentrate." In addition, Plaintiff alleges that it "largely created the burgeoning

market for genuine pomegranate juice," by educating the public about health claims through its advertisements and/or promotions. Many of Plaintiff's health claims are not supported by any substantial scientific evidence. Indeed, by Plaintiff's own admission, many of its advertising claims constitute mere "puffery." Thus, Plaintiff is seeking to capitalize in this case on the fruits of its own misconduct in the form of misleading labeling and advertising.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

(Reservation)

Further responding, TCCC states that it currently has insufficient knowledge or information on which to form a belief as to whether it may have additional, as yet unstated, affirmative defenses available. TCCC reserves the right to assert additional affirmative defenses in the event that discovery indicates it would be appropriate.

PRAYER

WHEREFORE, TCCC prays for judgment as follows:

1. That Plaintiff takes nothing by way of the Complaint;

2. That the Complaint be dismissed with prejudice and judgment entered in favor of TCCC;

3. That TCCC be awarded its costs, disbursements and attorneys' fees in this action; and

4. For such other and further relief as this Court deems just and proper.

DATED: September 30, 2009 MUNGER, TOLLES & OLSON LLP

MARC T.G. DWORSKY
GREGORY D. PHILLIPS
MARTIN D. BERN
ALISON J. MARKOVITZ

By: */s/ Martin D. Bern*
MARTIN D. BERN
Attorneys for Defendant
The Coca-Cola Company

DEMAND FOR JURY TRIAL

Pursuant to Fed. R. Civ. P. 38(b), Defendant demands a trial by jury of all triable issues and affirmative defenses herein.

DATED: September 30, 2009

MUNGER, TOLLES & OLSON LLP
MARC T.G. DWORSKY
GREGORY D. PHILLIPS
MARTIN D. BERN
ALISON J. MARKOVITZ

By: */s/ Martin D. Bern*
MARTIN D. BERN
Attorneys for Defendant
The Coca-Cola Company

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

POM WONDERFUL LLC,
a Delaware limited liability company,
Plaintiff,

v.

THE COCA COLA COMPANY,
a Delaware corporation; and DOES 1-10, inclusive
Defendants.

Case No. CV-08-06237 SJO (FMOx)
Hon. S. James Otero
Hearing:
Date: January 25, 2010
Time: 10:00 a.m.
Place: Courtroom 1– 2nd Floor

DECLARATION OF E. DEBORAH JAY IN OPPOSITION TO DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

DECLARATION OF E. DEBORAH JAY, PH.D

I, E. Deborah Jay, declare as follows:

1. I am President and Chief Executive Officer of Field Research Corporation ("Field Research"), a San Francisco-based research firm specializing in marketing and public opinion surveys. I make this declaration in support of plaintiff Pom Wonderful LLC's ("Pom") opposition to the motion for summary judgment filed by defendant The Coca-Cola Company ("TCCC").

2. Attached as Exhibit A is a true and correct copy of my expert witness report in this action, dated November 12, 2009 and entitled the Beverage Survey Report (Minute Maid® 100% Fruit Juice Blend Pomegranate Blueberry) (the "Field Survey Report"). Copies of the Field Survey Report were provided to TCCC's counsel. The Field Survey Report discloses my expert opinion in connection with this litigation, which is summarized in relevant part below.

3. I have more than 30 years of experience conducting large-scale surveys of all types (e.g., mail, telephone and in-person), including surveys for public agencies, nonprofit organizations, private companies and law firms. I have conducted numerous surveys on behalf of both plaintiffs and defendants in trademark and advertising disputes. I have testified in state and federal courts and have been qualified by several courts as an expert in survey methodology.

4. I hold a bachelor's degree in psychology and political science from the University of California at Los Angeles (magna cum laude) and a master's degree and doctorate in political science from the University of California at Berkeley. Before joining Field Research in 1991, I was a program director at SRI International (formerly Stanford Research Institute). I also was a manager with KPMG Peat Marwick in San Francisco, and a research associate at the Survey Research Center at the University of California at Berkeley. I have lectured to classes at UC Berkeley's Haas School of Business (at the graduate and undergraduate levels) and at Boalt Law School, and have served on the faculty of various continuing legal education programs.

5. I am past chair of the Council of American Survey Research Organizations (CASRO), a not-for-profit

trade association representing over 200 survey research companies engaged in professional research. I served as a director of CASRO for seven years (from 1995 to 2001) and during that time chaired both the Survey Research Quality and Standards and Ethics committees of that organization.

6. I served on the Executive Council of the American Association for Public Opinion Research (AAPOR), a professional society of individuals engaged in opinion research, market research, and social research. I was elected Standards Chair of the national organization, served as president of the Pacific Chapter of AAPOR, and am a member of the advisory committee for Public Opinion Quarterly, an official publication of AAPOR. Founded in 1947, AAPOR's membership includes approximately 2,000 individuals from every sector of the research community, including academic institutions, commercial organizations, government agencies and nonprofit organizations.

7. Founded in 1945 by Mervin Field, Field Research currently conducts thousands of interviews each year with representative samples of the general public, consumers, employees, corporate executives, and other populations. Field Research has conducted the nationally-quoted Field Poll since 1947, and has tracked voter preferences in all major statewide elections in California since 1948. Since 1948, the average deviation between The Field Poll's final pre-election poll in California and the actual percentage vote in California for the winning candidate in elections for President, Governor and U.S. Senate has been approximately two percentage points. The Field Poll is well-known throughout California for the surveys it regularly takes and publishes on issues of public importance.

8. Field Research was retained by Pom's counsel to conduct a survey (the "Field Survey") with a nationwide representative sample of adults age 18 and older who were potential purchasers of pomegranate and blueberry juice blends ("juice blend purchasers"). The survey measured consumer perceptions of Minute Maid® 100% Fruit Juice Blend Pomegranate Blueberry ("Minute Maid® Pomegranate Blueberry" juice blend), which I understand does not mainly contain pomegranate and blueberry juice. The purpose of the survey was to determine whether juice blend purchasers are likely to mistakenly believe that the main ingredients in Minute Maid® Pomegranate Blueberry juice blend are pomegranate and blueberry juice (and not other types of fruit juice) and, if so, whether this is due to the packaging (the words "Pomegranate Blueberry" on the front of the bottle and the inclusion of "Pomegranate Blueberry" in the product name on the back of the bottle).

9. For the Field Survey, 538 face-to-face interviews were completed with potential purchasers of pomegranate and blueberry juice blends. The interviews for the survey were double-blind: neither the interviewing staff nor the survey respondents were told the name of the client, or that the survey might be used in connection with a dispute (or litigation). Approximately half the qualifying survey respondents (271 survey respondents) were in the "test" group. This group was shown the actual Minute Maid® Pomegranate Blueberry juice blend bottle that was sold in retail stores at the time the survey was conducted (the "test" bottle). The other half of qualifying survey respondents (267 survey respondents) served as a "control" group and was shown a modified Minute Maid® Pomegranate Blueberry juice blend bottle. The modified

bottle was similar to the actual Minute Maid® Pomegranate Blueberry juice blend bottle (the "test" bottle) except that the words "Pomegranate Blueberry" on the front of the juice bottle and in the product name on the back of the bottle were removed.

10. Survey respondents were asked three basic sets of questions. The first basic set of questions concerned the main messages communicated by the package about the product. The second basic set of questions asked survey respondents whether they thought the package communicated that the product contained fruit juice and, if so, which types of fruit juice the product contained. The third basic set of questions inquired whether survey respondents thought the package communicated the types of fruit juice the product mainly contained and, if so, which types of fruit juice it mainly contained. Survey respondents also were asked the reasons for their answers in response to the second and third sets of questions.

11. When asked the types of fruit juice the product contains, 14% of survey respondents in the "test" group mentioned pomegranate and blueberry juice only. The comparable percentage for the "control" group was less than 1% (a difference of approximately 13 percentage points between the "test" group and the "control" group).

12. When asked the types of fruit juice the product mainly contains, 36% of survey respondents in the "test" group mentioned pomegranate and blueberry juice only. The comparable percentage for the "control" group was 1% (a difference of 35 percentage points between the "test" group and the "control" group).

13. When asked the reasons for their answer, 32% of survey respondents in the "test" group said the product mainly contains pomegranate and blueberry juice only and gave one or more of the following reasons related to the packaging: they referred to the words "pomegranate blueberry" on the bottle, the label and/or they indicated that the bottle said this. None of the survey respondents in the "control" group responded in this manner.

14. It is my opinion, based on my analysis of the Field Survey, my professional experience, and my education, that the Field Survey supports the conclusion that a substantial proportion of potential purchasers of pomegranate and blueberry juice blends are likely to mistakenly believe that Minute Maid® Pomegranate Blueberry juice blend mainly contains pomegranate and blueberry juice (and not other types of fruit juice) due to the packaging (the words "pomegranate blueberry" on the front of the bottle and in the product name on the back of the bottle).

15. As I testified during my January 4, 2010 deposition in this action, I am prepared to testify at trial regarding the Field Survey's measure of consumer perceptions of TCCC's naming of its Minute Maid® Pomegranate Blueberry juice blend.

16. I have reviewed content that TCCC's website displays regarding its Minute Maid® Pomegranate Blueberry juice blend. In my opinion, several of the website pages depict the Minute Maid® Pomegranate Blueberry juice blend in a way that communicates the same commercial impression as the product's bottle does.

17. To the extent that TCCC's website communicates the same commercial impression of the Minute

Maid Enhanced Pomegranate Blueberry product as the bottle does, my opinion is that the website includes misleading elements.

18. Attached as Exhibit B is a true and correct copy of excerpts from the transcript for my January 4, 2010 deposition.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct and that this declaration was executed in San Francisco, California on this 8th day of January 2010.

/s/ E. Deborah Jay
E. Deborah Jay, Ph.D

EXHIBIT A

Beverage Survey Report
(Minute Maid®
100% Fruit Juice Blend
Pomegranate Blueberry)

– November 2009 –

FIELD
RESEARCH
CORPORATION

* * *

Report of E. Deborah Jay, Ph.D.

I. Introduction and Summary

I am President and Chief Executive Officer of Field Research Corporation ("Field Research"), a San Francisco-based research firm specializing in marketing and public opinion surveys. Field Research was retained by counsel for Pom Wonderful LLC to conduct a survey (the "Field Survey") with a nationwide representative sample of adults age 18 and older who were potential purchasers of pomegranate and blueberry juice blends ("juice blend purchasers"). The survey measured consumer perceptions of Minute Maid® 100% Fruit Juice Blend Pomegranate Blueberry ("Minute Maid® Pomegranate Blueberry" juice blend), which I understand does not *mainly* contain pomegranate and blueberry

juice. The purpose of the survey was to determine whether juice blend purchasers are likely to mistakenly believe that the *main* ingredients in Minute Maid® Pomegranate Blueberry juice blend are pomegranate and blueberry juice (and not other types of fruit juice) and, if so, whether this is due to the packaging (the words "Pomegranate Blueberry" on the front of the bottle and the inclusion of "Pomegranate Blueberry" in the product name on the back of the bottle).

For the Field Survey, 538 face-to-face interviews were completed with potential purchasers of pomegranate and blueberry juice blends. To qualify for the Field Survey, adults had to be age 18 and older, and they had to think that they would purchase a pomegranate juice blend and a blueberry juice blend in the next 3 months.

The interviews for the Field Survey were conducted between April 9 and May 14, 2008, by 83 professionally-trained interviewers at 17 shopping malls in 13 states (located in the northeastern, midwestern, southern and western United States). Approximately half the qualifying survey respondents (271 survey respondents) were in the "test" group. This group was shown the actual Minute Maid® Pomegranate Blueberry juice blend bottle that was sold in retail stores at the time the survey was conducted (the "test" bottle). The other half of qualifying survey respondents (267 survey respondents) served as a "control" group and was shown a modified Minute Maid® Pomegranate Blueberry juice blend bottle. The modified bottle was similar to the *actual* Minute Maid® Pomegranate Blueberry juice blend bottle (the "test" bottle) except that the words "Pomegranate Blueberry" on the front of the juice bottle and in the product name on the back of the bottle were removed.

The results for the "test" group were compared with the results for the "control" group to determine whether there was the same or a different number of persons who mistakenly thought the product's *main* ingredients were pomegranate and blueberry juice (and not other types of fruit juice). The "control" group provided a measure of the extent to which pomegranate and blueberry juice mentions in the "test" group were due to reasons unrelated to the packaging, such as guessing and other sources of "noise."

At the beginning of the interview, survey respondents were asked to look at one Minute Maid® Pomegranate Blueberry juice blend bottle (either the "test" bottle or the "control" bottle). Survey respondents were asked to look at the product the way they normally do when they shop for beverages. After survey respondents were asked to look at the juice blend bottle, interviewers posed a series of open-ended questions (*i.e.*, questions that required survey respondents to answer in their own words) and closed-ended questions (*i.e.*, questions for which response categories were provided). Before posing the survey questions, interviewers told the survey respondents that there was no right or wrong answer and to indicate if they did not have an opinion.

Survey respondents were asked three basic sets of questions. The first basic set of questions concerned the main messages communicated by the package about the product. The second basic set of questions asked survey respondents whether they thought the package communicated that the product contained fruit juice and, if so, which types of fruit juice the product contained. The third basic set of questions inquired whether survey respondents thought the package communicated the types of fruit juice the product

mainly contained and, if so, which types of fruit juice it *mainly* contained. Survey respondents also were asked the reasons for their answers in response to the second and third sets of questions.

The interviews for the Field Survey were double-blind; neither the interviewers nor the survey respondents were told the name of the client or that the survey might be used in connection with a dispute (or litigation). The interviews for the Field Survey were conducted according to accepted survey standards. Based on the overall design and execution of the Field Survey, it provides representative information concerning potential purchasers of pomegranate and blueberry juice blends.

As described in more detail in the discussion which follows, the Field Survey found:

- When asked the main messages communicated by the package, most survey respondents gave one or more of the following responses (or words to that effect): the product is healthy, nutritious, nourishes your brain, is good for you, has Omega-3/DHA or has other vitamins and nutrients (87% for the "test" group and 87% for the "control" group).
- When asked the types of fruit juice the product contains, 14% of survey respondents in the "test" group mentioned pomegranate and blueberry juice only. The comparable percentage for the "control" group was less than 1% (a difference of approximately 13 percentage points between the "test" group and the "control" group).
- When asked the types of fruit juice the product *mainly* contains, 36% of survey respondents in the "test" group mentioned pomegranate and blueberry

juice only. The comparable percentage for the "control" group was 1% (a difference of 35 percentage points between the "test" group and the "control" group).

- When asked the reasons for their answer, 32% of survey respondents in the "test" group said the product *mainly* contains pomegranate and blueberry juice only *and* gave one or more of the following reasons related to the packaging: they referred to the words "pomegranate blueberry" on the bottle, the label and/or they indicated that the bottle said this. None of the survey respondents in the "control" group responded in this manner.

It is my opinion, based on my analysis of the Field Survey, my professional experience, and my education, that the Field Survey supports the conclusion that a substantial proportion of potential purchasers of pomegranate and blueberry juice blends are likely to mistakenly believe that Minute Maid® Pomegranate Blueberry juice blend *mainly* contains pomegranate and blueberry juice (and not other types of fruit juice) due to the packaging (the words "pomegranate blueberry" on the front of the bottle and in the product name on the back of the bottle).

The survey methods, findings, and my conclusions are described in the remainder of this report, which is based on information that I have been provided and analyses that I have performed thus far. I understand that I may be provided with additional information. I also may be asked to perform further analyses and, if so, this report may be amended or revised.

II. Credentials

I am President and CEO of Field Research, one of the oldest and most respected marketing and public opinion research firms in the United States. I bring to this project more than 30 years of experience conducting large-scale surveys of all types (*e.g.*, mail, telephone and in-person), including surveys for public agencies, nonprofit organizations, private companies and law firms. I have conducted numerous surveys on behalf of both plaintiffs and defendants in trademark and advertising disputes. I have testified in state and federal courts and have been qualified by several courts as an expert in survey methodology.

I hold a bachelor's degree in psychology and political science from the University of California at Los Angeles (*magna cum laude*) and a master's degree and doctorate in political science from the University of California at Berkeley. Before joining Field Research in 1991, I was a program director at SRI International (formerly Stanford Research Institute). I also was a manager with KPMG Peat Marwick in San Francisco, and a research associate at the Survey Research Center at the University of California at Berkeley. I have lectured to classes at UC Berkeley's Haas School of Business (at the graduate and undergraduate levels) and at Boalt Law School, and have served on the faculty of various continuing legal education programs.

I am past chair of the Council of American Survey Research Organizations (CASRO), a not-for-profit trade association representing over 200 survey research companies engaged in professional research. I served as a director of CASRO for seven years (from 1995 to 2001) and during that time chaired both the

Survey Research Quality and Standards and Ethics committees of that organization.

I served on the Executive Council of the American Association for Public Opinion Research (AAPOR), a professional society of individuals engaged in opinion research, market research, and social research. I was elected Standards Chair of the national organization, served as president of the Pacific Chapter of AAPOR, and am a member of the advisory committee for *Public Opinion Quarterly*, an official publication of AAPOR. Founded in 1947, AAPOR's membership includes approximately 2,000 individuals from every sector of the research community, including academic institutions, commercial organizations, government agencies and nonprofit organizations.

Founded in 1945 by Mervin Field, Field Research currently conducts thousands of interviews each year with representative samples of the general public, consumers, employees, corporate executives, and other populations. Field Research has conducted the nationally-quoted *Field Poll* since 1947, and has tracked voter preferences in all major statewide elections in California since 1948. Since 1948, the average deviation between *The Field Poll*'s final pre-election poll in California and the actual percentage vote in California for the winning candidate in elections for President, Governor and U.S. Senate has been approximately two percentage points. *The Field Poll* is well-known throughout California for the surveys it regularly takes and publishes on issues of public importance.

III. Prior Testimony

During the past four years, I have testified in deposition and/or at trial in the following cases:

- Autodesk v. Dassault Systemes Solidworks Corporation (United States District Court, Northern District of California).
- National Envelope Corporation v. American Pad and Paper LLC. (United States District Court, Southern District of New York).
- City of Seattle v. Professional Basketball Club LLC. (United States District Court, Western District of Washington).
- S.C. Johnson & Son, Inc. v. Buzz Off Insect Shield, LLC. and International Garment Technologies (United States District Court, Middle District of North Carolina).
- Merisant Company v. McNeil Nutritionals and McNeil PPC-Inc. (United States District Court, Eastern District of Pennsylvania).
- Nissan Motor Co. v. Nissan Computer Corp. (United States District Court, Central District of California).
- In re FedEx Ground Package System Inc. Employment Practices Litigation (United States District Court, Northern District of Indiana).
- Kargo Global, Inc. v. Advance Magazine Publishers, Inc. (United States District Court, Southern District of New York).
- Enterprise Rent-A-Car v. U-Haul International Inc. and eMove Inc. (United States District Court, Eastern District of Missouri).
- Sutter Health, et. al., v. Unite Here (Superior Court of the State of California, Placer County).

- Ty Inc., v. Softbelly's Inc. (United States District Court, Northern District of Illinois).

IV. Publications

A list of publications, publicly released technical reports, and conference papers/presentations I have authored or coauthored during the past 10 years is included in Appendix A.

V. Expert Compensation

Field Research is performing this study on a time and materials basis. Because work in connection with this project is ongoing, I do not yet know the total project costs. The hourly rate that Field Research is charging for my time on this project in 2009 is $500.

VI. Materials Provided

I was provided with copies of the following: (1) the complaint and the first amended complaint filed by plaintiff in this action; (2) the order granting in part and denying in part defendant's motion to dismiss (dated February 10, 2009); and (3) the order denying defendant's motion to dismiss plaintiff's first amended complaint (dated September 15, 2009).

VII. Survey Design and Approach

Under my design, direction, and supervision, Field Research conducted a survey with a nationwide representative sample of adults age 18 and older who were potential purchasers of pomegranate and blueberry juice blends. The survey measured consumer perceptions of Minute Maid® Pomegranate Blueberry juice blend, which I understand does not *mainly* contain pomegranate and blueberry juice. The purpose of the survey was to determine whether juice blend purchas-

ers are likely to mistakenly believe that the *main* ingredients in Minute Maid® Pomegranate Blueberry juice blend are pomegranate and blueberry juice (and not other types of fruit juice) and, if so, whether this is due to the packaging (the words "Pomegranate Blueberry" on the front of the bottle and the inclusion of "Pomegranate Blueberry" in the product name on the back of the bottle).

A. Sampling Approach

For the Field Survey, 538 face-to-face interviews were completed with potential purchasers of pomegranate and blueberry juice blends.[1] Approximately half the qualifying survey respondents (271 survey respondents) were in the "test" group. This group was shown the actual Minute Maid® Pomegranate Blueberry juice blend bottle that was sold in retail stores at the time the survey was conducted (the "test" bottle). The other half of qualifying survey respondents (267 survey respondents) served as a "control" group and was shown a modified Minute Maid® Pomegranate Blueberry juice blend bottle. The modified bottle was similar to the *actual* Minute Maid® Pomegranate Blueberry juice blend bottle (the "test" bottle) except that the words "Pomegranate Blueberry" on the front of the juice bottle and in the product name on the back of the bottle were removed.

The results for the "test" group were compared with the results for the "control" group to determine whether there was the same or a different number of persons who mistakenly thought the product's *main* ingredients were pomegranate and blueberry juice (and not other types of fruit juice). The "control" group provided a measure of the extent to which pomegranate and blueberry juice mentions in the "test" group were

due to reasons unrelated to the packaging, such as guessing and other sources of "noise."

The interviews for the Field Survey were conducted at 17 shopping malls in 13 states (located in the northeastern, midwestern, southern, and western United States). Listed below are the geographic locations and shopping malls where the face-to-face interviews were conducted.[2]

- **Northeast**
  - *Massachusetts: Boston Metropolitan Area*

    Dartmouth Mall in Dartmouth, Massachusetts
    Faneuil Hall Marketplace in Boston, Massachusetts
  - *New Jersey: Philadelphia Metropolitan Area*

    Moorestown Mall in Moorestown, New Jersey
  - *New York: Rochester Metropolitan Area*

    Market Place Mall in Rochester, New York
- **West**
  - *Arizona: Tucson Metropolitan Area*

    Foothills Mall in Tucson, Arizona
  - *California: Los Angeles Metropolitan Area*

    Montclair Plaza in Montclair, California
  - *Colorado: Denver Metropolitan Area*

    Colorado Mills Mall in Lakewood, Colorado
- **Midwest**
  - *Illinois: Chicago Metropolitan Area*

    Hawthorn Center in Vernon Hills, Illinois

Lincolnwood Town Center in Lincolnwood, Illinois

– *Minnesota: Minneapolis Metropolitan Area*

Southdale Center in Edina, Minnesota

- South

– *Florida: Miami/Ft. Lauderdale Metropolitan Area*

Broward Mall in Plantation, Florida

– *Georgia: Atlanta Metropolitan Area*

Perimeter Mall in Atlanta, Georgia

– *Maryland: Baltimore Metropolitan Area*

Arundel Mills Mall in Hanover, Maryland
Lakeforest Mall in Gaithersburg, Maryland

– *North Carolina: Charlotte Metropolitan Area*

Concord Mills Mall in Concord, North Carolina

– *Texas: Dallas Metropolitan Area*

The Shops at Willow Bend in Plano, Texas
Six Flags Mall in Arlington, Texas

Four interviewing services provided the research facilities and interviewers for the mall survey: (1) Carlene Research, (2) Boston Field & Focus/Performance Plus, (3) CRG Global Inc./ Cunningham Field and Service, and (4) Friedman/Consumer Opinion Center. Carlene Research had research facilities at more than one mall. The research facilities at each mall satisfied the following criteria:

- Had consumer research experience.

- Employed their own interviewers and provided local supervision to monitor interviewers.
- Had private interviewing rooms where survey respondents could be interviewed "off the mall."
- Assigned multiple interviewers to the project, and permitted Field Research project staff to train their supervisors and interviewers.
- Reported to Field Research daily during data collection, and permitted Field Research to independently verify their interviewers' work.

The sampling plan included age and gender quotas designed to ensure that adults in different demographic groups were adequately represented and that the samples for the survey were representative of pomegranate and blueberry juice blend purchasers. The sampling quotas were based on questions Field Research added to a telephone survey conducted by Opinion Research Corporation (ORC) with a nationwide random sample of 1,001 adults concerning juice blend purchases.[3] The interviews for the ORC telephone survey were conducted between March 27 and March 30, 2008. The telephone survey included 195 adults who thought they would purchase a pomegranate or blueberry juice blend in the next 3 months, and who said that they were responsible for deciding which brands to purchase. Based on the demographics of these 195 adults, Field Research specified that for the mall survey, a little over half (55%) of the interviews with qualified adults were to be completed with women and the remainder (45%) were to be completed with men. Approximately 39% of the interviews with qualified adults were to be completed with adults age 18 to 34, 27% with adults age 35 to 49, and 34% with adults age 50 and older. Consistent with the Census distribution for

the U.S. adult population, slightly more than one-third of the interviews with qualified adults were to be conducted in the South, and approximately one-fifth of the interviews were to be completed in each of the other three regions of the United States (the Northeast, Midwest, and West).

B. Initial Screening Interviews and Eligibility Criteria

To identify eligible survey respondents, interviewers were instructed to approach adult shoppers at each shopping mall in a systematic manner until each age/gender quota was filled. They then asked adults the following questions:

- "Do you ever purchase any of the following types of bottled beverages?"
  - Energy drinks,
  - Tea drinks,
  - Fruit juice drinks,
  - Diet soda?"
- (*IF EVER PURCHASES FRUIT JUICE DRINKS*) "During the past 3 months, did you, personally, purchase any bottled drink with a combination or blend of fruit juices or fruit juice flavors?"
- (*IF HAD PURCHASED FRUIT JUICE BLENDS IN THE PAST 3 MONTHS*) "During the past 3 months, which of the following type or types of juice blends did you purchase?"
  - An apple juice blend,
  - A blueberry juice blend,
  - A cranberry juice blend,
  - A grape juice blend,
  - A pineapple juice blend,

- A pomegranate juice blend,
- A plum juice blend,
- A raspberry juice blend?"

- "During the next 3 months, do you think that you, personally, will purchase any bottled drink with a combination or blend of fruit juices or fruit juice flavors?"

- (*IF WILL PURCHASE FRUIT JUICE BLENDS IN THE NEXT 3 MONTHS*) "During the next 3 months, which of the following type or types of juice blends do you think you will purchase?"

  - An apple juice blend,
  - A blueberry juice blend,
  - A cranberry juice blend,
  - A grape juice blend,
  - A pineapple juice blend,
  - A pomegranate juice blend,
  - A plum juice blend,
  - A raspberry juice blend?"

- (*IF WILL PURCHASE FRUIT JUICE BLENDS IN THE NEXT 3 MONTHS*) "Are you or is someone else mainly responsible for deciding which brand or brands of juice blends to purchase?"

- "Do you or does anyone in your household...

  - Work at this mall,
  - Work for a company that makes or sells beverages,
  - Work in marketing research or advertising research?"

- "During the past 3 months, have you participated in a survey at a mall?"

- "Do you know anyone who has participated in this survey or did anyone tell you about this survey before now?"
- "Do you live in this area or are you visiting from somewhere else?"
- "When you shop for beverages, do you usually wear contact lenses or eyeglasses?" and, if so, "Do you have the contact lenses or eyeglasses with you that you usually wear when you shop for beverages?"

To qualify for the survey, adults age 18 and older had to purchase bottled fruit juice drinks, they had to think that they would purchase a pomegranate juice blend and a blueberry juice blend during the next 3 months, and they had to decide (either by themselves or with someone else) which brands to purchase.

Other criteria that qualifying adults were required to satisfy include the following:

- Not work or live in a household in which someone works (a) at the mall where the interview was conducted; (b) for a company that makes or sells beverages; or (c) in marketing research or advertising research.
- Not have participated in a survey at a mall during the past 3 months.
- Not know anyone who had participated in the survey or have been told about the survey before being interviewed.
- Live in the area where the mall was located.

- If the adult usually wears contact lenses or eyeglasses when shopping for beverages, the adult had to have these with him/her.

At the end of the screening interview, eligible adults were told the following:

> "For the second part of this study, I would like to show you a product and ask you a few questions. To do this, I need to take you to our interviewing room. This will take only a few minutes, and in appreciation for your cooperation we will pay you $5."

Eligible adults who agreed to be interviewed were taken to the interviewing service's facility at the mall where the questionnaire was administered.

C. Questionnaire and Survey Administration

At the beginning of the interview, interviewers asked the survey respondent to be seated and to put on contact lenses or eyeglasses if he/she normally wears them when shopping for beverages. Interviewers handed survey respondents one bottle (either the "test" bottle or the "control" bottle), and said:

- "First, I would like to show you a product, and then I will ask you a few questions."

  - "Please look at this product the way you normally do when you shop for beverages. Take as long as you like and tell me when you are finished."

After survey respondents said they were finished looking at the product, interviewers instructed them in the following manner:

> "I would like to ask you a few questions about the product I just showed you. Before I begin, I would

like to assure you that there is no right or wrong answer. If you do not have an opinion, please say so."

Interviewers then posed the first set of questions about the product survey respondents were shown:

- "What message or messages does this package mainly communicate to you about this product?"
- "Anything else?"

The second set of questions concerned whether the product contained fruit juice and included the following questions:

- "Now, I am going to read you a question that has the following three answer choices. Please allow me to read the whole question before answering. After I am done, if you would like me to repeat the question, just ask me. Based on the package, do you think...
  - One, this product does contain fruit juice,
  - Two, this product does not contain fruit juice, or
  - Three, do you have no opinion?"[4]

(*IF THE RESPONDENT INDICATED THAT THE PRODUCT DOES CONTAIN FRUIT JUICE*)

- "Based on the package, what type or types of fruit juice do you think this product contains?"
- "What about the package makes you think this product contains the type or types of fruit juice you mentioned?"
- "Anything else?"

Those survey respondents who said the product does contain fruit juice were asked a third set of questions:

- "Now, I am going to read you another question that has three answer choices. Once again, if you would like me to repeat the question, just ask me. Do you think...
  - One, this package does communicate the type or types of fruit juice it mainly contains,
  - Two, this package does not communicate the type or types of fruit juice it mainly contains, or
  - Three, do you have no opinion?"[5]

(*IF THE RESPONDENT INDICATED THAT IT DOES COMMUNICATE THE TYPES OF FRUIT JUICE THE PRODUCT MAINLY CONTAINS*)

- "What type or types of fruit juice does this product mainly contain?"
- "What about the package makes you think this product mainly contains the type or types of fruit juice you mentioned?"
- "Anything else?"

At the end of the survey, interviewers confirmed the age and gender of survey respondents and obtained information for verification purposes.

The following materials were developed and used for the Field Survey: Supervisor Instructions, Interviewer Instructions, Screening Forms, Questionnaires and Answer Sheets (for eligible adults), and Responses to General Questions. (Copies of these materials and photographs of the "test" bottle and the "control" bottle are included in Appendix B.) The Supervisor In-

structions and Interviewer Instructions provided detailed information about how to administer the survey instruments. The Responses to General Questions provided background information about Field Research and included responses for anticipated questions. Before interviewing began, Field Research project staff reviewed each of the survey materials with local supervisors and interviewers during training sessions.

In all, 538 face-to-face interviews with eligible adults were completed for the Field Survey. Interviews for the survey were conducted by 83 professionally trained interviewers between April 9 and May 14, 2008. The interviews for the survey were double-blind: neither the interviewing staff nor the survey respondents were told the name of the client, or that the survey might be used in connection with a dispute (or litigation).

Under my direction and supervision, Field Research survey supervisors, word processors, data processors, and programmers processed the data from the completed questionnaires. After the data initially were entered in the computer, Field Research's project staff proofed the original questionnaires against computer printouts of verbatim responses to ensure that the data file was accurate. During data collection, survey respondents were asked their name and telephone number so that Field Research could independently verify their participation. Field Research was able to reach 67% of the eligible adults who participated in the survey by telephone within a week or so after they completed an interview and independently verify that they had participated in the survey.[6]

D. Characteristics of Survey Respondents

Respondents for the Field Survey were recruited and interviewed in shopping malls. This survey approach allowed interviewers to show a product (either the "test" bottle or the "control" bottle") to a nationwide representative sample of potential purchasers of pomegranate and blueberry juice blends, and then ask a series of questions about the product. Marketing and advertising research often is conducted in this manner. The sample for the Field Survey is not a probability sample (*i.e.*, the probability of an adult being intercepted at a particular location in a particular mall is unknown). Therefore, quotas were set to ensure that the survey respondents were representative of potential purchasers of pomegranate and blueberry juice blends.

Table 1 compares the age and gender distribution for the following three groups: (1) pomegranate and blueberry juice blend purchasers in the U.S. (based on the ORC telephone survey); (2) adults interviewed for the Field Survey about the "test" bottle; and (3) adults interviewed about the "control" bottle. As shown in Table 1, the age and gender distribution for each of the three groups is similar.

Table 1
Age and Gender Characteristics of U.S. Pomegranate and Blueberry Juice Blend Purchasers and for Field Survey Respondents in the "Test" Group and in the "Control" Group

	U.S. Juice Blend Purchasers* (n = 195)	"Test" Group (n = 271)	"Control" Group (n = 267)
Gender	45%	44%	44%
Men	55	56	56

Women			
Age			
18 to 34	39%	38%	39%
35 to 49	27	28	29
50 and older	34	34	32

* *Based on a telephone survey conducted by ORC with a nationwide random sample of adults who thought they would purchase a pomegranate or blueberry juice blend in the next 3 months and who were personally responsible for deciding which brands to purchase.*

Table 2 compares the regional distribution for the following three groups: (1) the U.S. adult population; (2) adults interviewed about the "test" bottle; and (3) adults interviewed about the "control" bottle for the Field Survey. As shown in Table 2, the regional distribution for the three groups is similar.

Table 2
Regional Distribution for the U.S. Adult Population and for Field Survey Respondents in the "Test" Group and in the "Control" Group

	U.S. Adult Population*	"Test" Group (n = 271)	"Control" Group (n = 267)
Region			
Northeast	18%	20%	21%
South	37	40	39
Midwest	22	20	20
West	23	20	20

* *Based on U.S. Census data (www.census.gov).*

To qualify for the Field Survey, adults had to be a potential purchaser of a pomegranate juice blend and a

blueberry juice blend (*i.e.*, they had to think that they would purchase a pomegranate juice blend and a blueberry juice blend in the next 3 months). As shown in Table 3, most survey respondents in the "test" group (75%) and in the "control" group (73%) also were past purchasers of pomegranate or blueberry juice blends (*i.e.*, they had purchased a pomegranate or blueberry juice blend in the past 3 months). A little over two-fifths of survey respondents in the "test" group (43%) and in the "control" group (44%) had purchased both types of fruit juice blends in the past 3 months.

Table 3
Whether Purchased a Pomegranate or a Blueberry Juice Blend in the Past 3 Months

	"Test" Group (n = 271)	"Control" Group (n = 267)
Had Purchased A Pomegranate or Blueberry Juice Blend	75%	73%
A pomegranate juice blend	68	63
A blueberry juice blend	51	53
Both types of fruit juice blends	43	44

**Based on S6.*

The interviews for the Field Survey were conducted according to accepted survey standards. Based on the overall design and execution of the Field Survey, it provides representative information concerning potential purchasers of pomegranate and blueberry juice blends.

VIII. Survey Results

In this section the results are described for survey respondents shown the "test" bottle (*i.e.*, the *actual*

Minute Maid® Pomegranate Blueberry juice blend bottle sold in retail stores at the time the survey was conducted) and for those shown the "control" bottle (*i.e.*, the *modified* Minute Maid® Pomegranate Blueberry juice blend bottle). A complete list of responses to the open-ended questions for each group is included in Appendices C through H.

A. Messages *Mainly* Communicated by the Package

Table 4 summarizes responses to the following questions for survey respondents shown the "test" bottle and for those shown the "control" bottle): "What message or messages does the package mainly communicate to you about this product?" and "Anything else?" As shown in Table 4, when asked the main messages communicated by the package, most survey respondents gave one or more of the following responses (or words to that effect): the product is healthy, nutritious, nourishes the brain, is good for you, has Omega-3/DHA or has other vitamins and nutrients (87% for the "test" group and for the "control" group).

Table 4
Main Messages Communicated by the Package about the Product

	"Test" Group (n = 271)	"Control" Group (n = 267)
It's healthy, nutritious, nourishes the brain, contains Omega 3/DHA or other vitamins and nutrients	87%	87%
It's 100% juice	24	22
It's a blend of fruits or juices	20	24
It's fruity, a fruit juice or juice	19	22
It's good	14	11
It's Minute Maid	9	7
The color	5	4
It's pomegranate or blueberry juice	9	3
Mentioned another type of fruit juice	3	5
Miscellaneous other comments	23	17

**Based on Q6a/b. Percentages add to more than 100% because some respondents gave more than one answer in response to these questions.*

B. What the Package Communicates About the Types of Fruit Juice the Product Contains

Survey respondents were asked whether based on the package they thought the product does or does not contain fruit juice (or whether the survey respondent did not have an opinion). As shown in Table 5, most survey respondents said that based on the package they thought the product did contain fruit juice (95% for the "test" group and for the "control" group).

Table 5
Whether the Product Contains Fruit Juice*

	"Test" Group (n = 271)	"Control" Group (n = 267)
This produce does contain fruit juice	95%	95%
This product does not contain fruit juice	3	1
No opinion	2	4

**Based on Q7.*

Those survey respondents who said that the product did contain fruit juice were asked the following question: "Based on the package, what type or types of fruit juice do you think this product contains?" As shown in Table 6, in response to this question, approximately 14% of survey respondents in the "test" group mentioned pomegranate and blueberry juice (and not other types of fruit juice). The comparable percentage for the "control" group was less than 1% (a difference of approximately 13 percentage points between the "test" group and the "control" group).

Table 6
Types of Fruit Juice the Product Contains*

	"Test" Group (n = 271)	"Control" Group (n = 267)
Pomegranate and blueberry juice only	14%	<1%
Pomegranate or blueberry juice only	1	<1
Pomegranate and/or blueberry juice and one or more other types of fruit juice	74	79
Did not mention pomegranate or blueberry juice	6	15
Not applicable – Did not say the product contains fruit juice	5	5

**Based on Q8.*

C. What the Package Communicates About the Types of Fruit Juice the Product *Mainly* Contains

Those survey respondents who said that the product did contain fruit juice were asked whether the package did or did not communicate the types of fruit juice the product *mainly* contains (or whether the survey respondent did not have an opinion). As shown in Table 7, most survey respondents said that the package did communicate the types of fruit juice the product *mainly* contains (88% for the "test" group and 82% for the "control" group).

Table 7
Whether the Package Communicates the Types of Fruit Juice The Product *Mainly* Contains*

	"Test" Group (n = 271)	"Control" Group (n = 267)
Does communicate the types of fruit juice it *mainly* contains	88%	82%
Does not communicate the types of fruit juice it *mainly* contains	3	6
No opinion	4	7
Not applicable – Did not say the product contains fruit juice	5	5

**Based on Q10.*

Those survey respondents who said the package did communicate the types of fruit juice the product *mainly* contains were asked the following question: "What type or types of fruit juice does this product mainly contain?" As shown in Table 8, in response to this question, 36% of survey respondents in the "test" group mentioned pomegranate and blueberry juice (and not any other types of fruit juice). The comparable percentage for the "control" group was 1% (a difference of 35 percentage points between the "test" group and the "control" group).

Table 8
Types of Fruit Juice the Product *Mainly* Contains*

	"Test" Group (n = 271)	"Control" Group (n = 267)
Pomegranate and blueberry juice only	36%	1%
Pomegranate or blueberry juice only	6	3
Pomegranate and/or blueberry juice and one or more other types of fruit juice	40	54
Did not mention pomegranate or blueberry juice	6	24
Not applicable – Did not say the package communicates the types of fruit juice the product *mainly* contains	7	13
Not applicable – Did not say the product contains fruit juice	5	5

**Based on Q11.*

D. Reasons Survey Respondents Thought the Product's *Main* Ingredients Are Pomegranate and Blueberry Juice (and Not Any Other Types of Fruit Juice)

Those survey respondents who said the package did communicate the types of fruit juice it *mainly* contains were first asked the types of fruit juice the product *mainly* contains, and then they were asked the following questions: "What about the package makes you think this product mainly contains the type or types of fruit juice you mentioned?" and "Anything else?" Table 9 summarizes the responses to these questions for

those survey respondents who said that the product *mainly* contains pomegranate and blueberry juice (and not any other types of fruit juice).

As shown in Table 9, 32% of survey respondents in the "test" group said the product *mainly* contains pomegranate and blueberry juice only *and* gave one or more of the following reasons related to the packaging: they referred to the words "pomegranate blueberry" on the bottle, the label, and/or they indicated that the bottle said this. None of the survey respondents in the "control" group responded in this manner.

Table 9
Reasons Survey Respondents Thought the Product *Mainly* Contains Pomegranate and Blueberry Juice (and Not Any Other Types of Fruit Juice)*

	"Test" Group (n = 271)	"Control" Group (n = 267)
Gave one or more of the following reasons related to the packaging: they referred to the words "pomegranate blueberry" on the bottle, the label, and/or they indicated that the bottle said this.	32%	0%
Only mentioned other reasons (*e.g.*, only referred to the color of the juice or the reference to Omega-3 and DHA on the package)	4	1
Not applicable - Did not say the product mainly contains pomegranate and blueberry juice only	64	99

*Based on Q11 and Q12a/b.

Table 10 summarizes the percentage of respondents in various demographic subgroups in the "test" group who said that the product *mainly* contains pomegranate and blueberry juice (and not any other types of fruit juice) for one or more of the following reasons related to the packaging: they referred to the words "pomegranate blueberry" on the bottle, the label, and/or they indicated that the bottle said this. As shown in Table 10, regardless of their demographic characteristics, 27% or more of survey respondents in the "test" group said the *main* ingredients in the product were pomegranate and blueberry juice (and not any other types of fruit juice) for various reasons related to the packaging.

Table 10
Percent Who Said the "Test" Product *Mainly* Contains Pomegranate and Blueberry Juice (and Not Any Other Types of Fruit Juice) for Various Reasons Related to the Packaging

Total (n = 271)	32%
Gender	
Men (n = 119)	29
Women (n = 152)	36
Age	
18 to 34 (n = 104)	33
35 to 49 (n = 76)	30
50 or older (n = 91)	34
Region	
Northeast (n = 55)	38
South (n = 107)	27
Midwest (n = 55)	33
West (n = 54)	37

*Based on Q11 and Q12a/b.

E. Verbatims for Survey Respondents Who Thought the Product *Mainly* Contains Pomegranate and Blueberry Juice (and Not Any Other Types of Fruit Juice)

Table 11 includes the verbatims for those survey respondents in the "test" group who said the product *mainly* contains pomegranate and blueberry juice (and not any other types of fruit juice), and their reasons for this. An asterisk (*) indicates those survey respondents who said they thought the product *mainly* contains pomegranate and blueberry juice (and not any other types of fruit juice) for one or more of the following reasons related to the packaging: they referred to the words "pomegranate blueberry" on the bottle, the label, and/or they indicated that the bottle said this.

Table 11
Responses for Survey Respondents in the "Test" Group Who Thought the Product *Mainly* Contains Pomegranate and Blueberry Juice (and Not Any Other Types of Fruit Juice)

RID	Q11	Q12a/b
1001*	I would guess the main juice would be pomegranate and blueberry.	Because it is stated on the label.
1003*	Pomegranate and blueberry.	The print.
1004*	Pomegranate and blueberry.	It's listed on the bottle.
1006*	Mainly pomegranate and blueberry.	Because it says it in bold.
1007*	Pomegranate and blueberry.	It is called pomegranate blueberry.
1011*	Pomegranate and blueberry.	It says pomegranate and blueberry.
1013*	Pomegranate and blueberries.	It says it right on the front.
1014	Pomegranate and blueberry.	Well, the – I don't know.
1018*	Blueberry and pomegranate.	It says on the front.
1021*	Pomegranate and blueberry.	It says it on the label, that it is pomegranate and blueberry flavored.
1026*	Pomegranate and blueberry.	It says it on the label.
1032*	Pomegranate and blueberry.	They are listed in all-cap letters, including photos, at the front.
1035*	Blueberry and pom-	The color mainly. The

Table 11
Responses for Survey Respondents in the "Test" Group Who Thought the Product *Mainly* Contains Pomegranate and Blueberry Juice (and Not Any Other Types of Fruit Juice)

	egranate.	label tells you so.
1037	Pomegranate and blueberry.	I saw a picture of a pomegranate and blueberries.
1038*	Pomegranate and blueberry.	Because it says it on the front, and the color of it.
1043*	Blueberry and pomegranate.	It has a picture of it and it tells you in words.
1048*	Pomegranate and blueberry.	The labeling. The picture on it.
1051	Pomegranate and blueberry.	Because I can see the juice.
1058*	Pomegranate and blueberry.	The picture. It says it right on there.
1059*	Pomegranate and blueberry.	It says so on the bottle.
1060*	Pomegranate and blueberry.	Because its name is pomegranate and blueberry.
1061*	Pomegranate and blueberries.	Because it says it on the label. The picture.
1062*	Pomegranate and blueberry.	It says on it, and says a blend of flavor juices.
1064*	Pomegranate, blueberry.	Because it's right on the label.
1065*	Pomegranate and blueberry.	It specifically mentions those two and lumps the other juice into a flavored blend of juices.
1069*	Pomegranate and	By the label.

Table 11
Responses for Survey Respondents in the "Test" Group Who Thought the Product *Mainly* Contains Pomegranate and Blueberry Juice (and Not Any Other Types of Fruit Juice)

	blueberry.	
1070*	Blueberry and pomegranate.	It says so on the package.
1071*	Blueberry and pomegranate.	The picture. The printed words.
1072*	Pomegranate and blueberry.	That is what is written. There is a picture.
1074*	Pomegranate and blueberry.	Because it is listed on the label.
1079	Pomegranate, blueberry.	The picture.
1080*	Blueberry and pomegranate.	Shows them on the label and says so.
1081*	Pomegranate and blueberry.	Because of the lettering on the bottom – it says pomegranate and blueberry.
1082*	Pomegranate and blueberry.	They are displayed on the bottle. The words pomegranate and blueberry are written on the bottle.
1086*	Pomegranate and blueberry.	Because it says so on the label and has a picture of them on the label.
1093*	Pomegranate and blueberry.	Because it's written on the label.
1098	Blueberries and pomegranates.	Color. The mix of colors. You can see the red from the pomegranates.

Table 11
Responses for Survey Respondents in the "Test" Group Who Thought the Product *Mainly* Contains Pomegranate and Blueberry Juice (and Not Any Other Types of Fruit Juice)

1099*	Blueberry and pomegranate.	It says it in writing, and the picture on the label.
1103*	Pomegranate and blueberry.	It states it on the label.
1104	Blueberry and pomegranate.	The pictures.
1105*	Pomegranate and blueberry.	It says so right on the bottle.
1108*	Blueberry and pomegranate.	It says that in bold print, and says a blend of five juices. It says 100% fruit juices.
1115*	Pomegranate and blueberry.	It says so.
1118*	Pomegranate and blueberry.	Those are the two names mentioned. The pomegranate is big, but the blueberries are small.
1120*	Mainly pomegranate and blueberry, because those are the only two mentioned in the text.	Because on the front, they're the only ones mentioned in the text form. I like the fruit in it.
1123*	Pomegranate and blueberry.	The writing and the picture.
1124*	Pomegranate and blueberry.	Those are in larger print.
1131*	Pomegranate and blueberry.	Because that is the only name of fruit it states on

Table 11
Responses for Survey Respondents in the "Test" Group Who Thought the Product *Mainly* Contains Pomegranate and Blueberry Juice (and Not Any Other Types of Fruit Juice)

		the label. It mentions it contains Omega-3/DHA
1133*	Pomegranate and blueberry.	It's spelled out in the front.
1139*	In big letters under the fruit, it says pomegranate and blueberry.	Because that's the only fruit names it says up front.
1142	I think pomegranate and blueberry.	The color. The picture.
1150*	Pomegranate and blueberry.	It says that on the label. There are pictures of them also.
1152*	Pomegranate and blueberry.	It says pomegranate and blueberry.
1155*	Pomegranate and blueberry.	It lists those in letters instead of the other ones.
1156*	Pomegranate and blueberry.	The label has the picture and the words say pomegranate blueberry. Also, shows fruit.
1160*	Pomegranate and blueberry.	It says so on the label.
1161*	Pomegranate and blueberry.	Listed by name under the picture.
1162*	Pomegranate and blueberry.	The label.
1163*	Seems to mainly contain blueberry	The picture and the wording on the front la-

Table 11
Responses for Survey Respondents in the "Test" Group Who Thought the Product *Mainly* Contains Pomegranate and Blueberry Juice (and Not Any Other Types of Fruit Juice)

	and pomegranate juice, with apple and grape as a base.	bel.
1164*	Pomegranate and blueberry.	It says so, and shows a picture of pomegranate and blueberry.
1169	Blueberry and pomegranate.	The color of the bottle. The ingredients on the back.
1172*	Pomegranate, blueberry.	It says pomegranate, blueberry. It also has a picture of it.
1173*	Pomegranate and blueberry.	Because it's printed on the label.
1174*	Pomegranate and blueberry.	Because you can see it in front of the label.
1177*	Pomegranate and blueberry.	Because it says pomegranate and blueberry in large print, and underneath it says flavored blend of five juices.
1180*	Pomegranate and blueberry.	Because they are the two that are worded on the package. And their picture, too.
1181*	Pomegranate and blueberry.	The picture and wording underneath.
1182*	Pomegranate and blueberry.	The label with the fruits.
1183*	Pomegranate and	It says so on the pack-

Table 11
Responses for Survey Respondents in the "Test" Group Who Thought the Product *Mainly* Contains Pomegranate and Blueberry Juice (and Not Any Other Types of Fruit Juice)

	blueberry.	age.
1185*	Pomegranate and blueberry.	It says it on the label.
1189*	Pomegranate, blueberry.	They're listed first.
1192*	Blueberry and pomegranate.	Bottle says so.
1195*	Pomegranate and blueberries. That's the main two that stick out to you.	You can see right on the package. I can read it. Color, and the picture on the front of the package.
1196*	It says pomegranate and blueberry, pretty big on the label.	That's really the only specific juices it mentions on the front.
1197*	Pomegranate and blueberry are the two main things.	It says it on the label, and the picture on the bottle shows it.
1198*	Pomegranate blueberry.	The words pomegranate and blueberry. The picture.
1201*	Pomegranate and blueberry is probably the main.	Because it's named Pomegranate Blueberry Minute Maid.
1210*	Pomegranate and blueberry.	It says so on the front.
1215*	Pomegranate and blueberry.	The color, and it says it.

Table 11
Responses for Survey Respondents in the "Test" Group Who Thought the Product *Mainly* Contains Pomegranate and Blueberry Juice (and Not Any Other Types of Fruit Juice)

1218*	Pomegranate and blueberry.	It's printed on the label.
1219*	Pomegranate and blueberry.	Below the picture of the fruit, it says pomegranate and blueberry.
1222*	Pomegranate and blueberry.	That's what's printed on the label.
1223*	Pomegranate and blueberry.	Because it's in bold letters, it is written pomegranate and blueberry, and under is in smaller print the other juices in it. The main juices are in bolder print and the larger amount ingredients are the larger print on the bottle.
1233*	Pomegranate and blueberry.	It's in all capital, bolded letters.
1236*	Blueberry and pomegranate.	The labeling on the front. The actual content of the bottle.
1237*	Pomegranate and blueberry.	Pomegranate and blueberry is written underneath the picture of the fruit.
1241*	Pomegranate and	The label.

Table 11
Responses for Survey Respondents in the "Test" Group Who Thought the Product *Mainly* Contains Pomegranate and Blueberry Juice (and Not Any Other Types of Fruit Juice)

	blueberry.	
1244*	Mainly pomegranate and blueberry.	Because it is printed, and can also see on the picture that they have that product.
1245*	Pomegranate and blueberry.	The picture, and it says so.
1246*	Pomegranate and blueberry.	Because of the writing on it. The picture on it.
1251*	Pomegranate and blueberry.	It says it in big letters at the bottom.
1252*	Pomegranate and blueberry.	It said so. It points out those two fruits specifically.
1254	Blueberry and pomegranate.	It's a clear package. You can see what you're getting. It is eye-appealing. It would stand out on the shelf.
1257*	Pomegranate and blueberry.	Tells it on the package.
1260*	Blueberry and pomegranate.	It shows those two, and says so on the bottle.
1261*	Pomegranate and blueberry.	Because it is written on there. 100% juice.
1267*	Pomegranate and blueberry.	It says it on the front

Table 11
Responses for Survey Respondents in the "Test" Group Who Thought the Product *Mainly* Contains Pomegranate and Blueberry Juice (and Not Any Other Types of Fruit Juice)

		label.
1268	Mainly contains blueberry and pomegranate.	The picture clearly illustrates this. Also, the color of the product is a giveaway.

Table 12 includes the verbatims for those survey respondents in the "control" group who said the product *mainly* contains pomegranate and blueberry juice (and not any other types of fruit juice), and their reasons for this.

Table 12
Responses for Survey Respondents in the "Control" Group Who Thought the Product *Mainly* Contains Pomegranate and Blueberry Juice (And Not Any Other Types of Fruit Juice)

RID	Q11.	Q12a/b.
2085	Pomegranate is the main, and blueberry is the main.	It says Omega-3 and DHA. Those are mostly in blueberries and pomegranates. That's it. Oh, actually the juice color looks like pomegranate juice, mostly.
2242	Pomegranate, blueberry.	The picture, the color.
2257	Blueberry and blueberry.	The picture on the bottle. The color of the juice.

IX. Conclusions

The interviews for the Field Survey were conducted according to accepted survey standards. Based on the overall design and execution of the Field Survey, it provides representative information concerning potential purchasers of pomegranate and blueberry juice blends.

It is my opinion, based on my analysis of the Field Survey, my professional experience, and my education, that the Field Survey supports the conclusion that a substantial proportion of potential purchasers of pomegranate and blueberry juice blends are likely to mistakenly believe that Minute Maid® Pomegranate Blueberry juice blend *mainly* contains pomegranate and blueberry juice (and not other types of fruit juice) due

to the packaging (the words "pomegranate blueberry" on the front of the bottle and in the product name on the back of the bottle).

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed this 12th day of November 2009 at San Francisco, California.

/s/ E. Deborah Jay
E. Deborah Jay, Ph.D.

ENDNOTES

[1] 15 adults (9 in the "test" group and 6 in the "control" group) were inadvertently interviewed even though they did not qualify based on their responses to the screening interviews (*e.g.*, they did not think they would purchase a pomegranate and a blueberry juice blend in the next 3 months, they knew somebody who had participated in the survey). Because these survey respondents were not eligible to be interviewed, their questionnaires were not included in the data analyses. Two additional survey respondents in the "test" group did not complete the entire interview, and their questionnaires were not included in the survey data for this reason (1 in the "test" group and 1 in the "control" group). If the questionnaires for these 17 survey respondents (the 15 ineligible adults and the 2 adults who had incomplete questionnaires) had been included in the analyses, the survey results would have been virtually identical.

[2] Interviews for the "test" bottle and for the "control" bottle were each conducted at 15 different shopping locations in 13 states. Interviews about the "test" bottle were conducted at every mall except for Arundel Mills Mall and Dartmouth Mall. Interviews about the "control" bottle were conducted at every mall except for Faneuil Hall Marketplace and Lakeforest Mall.

[3] Opinion Research Center (ORC) is a survey research firm with offices in Princeton, New Jersey, and it is a member of the Council of American Survey Research Organizations. The following questions were included in the ORC telephone survey for purposes of determining sampling quotas for the mall survey conducted by Field Research:

- "During the past 3 months, did you, personally, purchase any bottled drink with a combination or blend of fruit juices or fruit juice flavors?"
- (*IF HAD PURCHASED FRUIT JUICE BLENDS IN THE PAST 3 MONTHS*) "During the past 3 months, which of the following type or types of juice blends did you purchase?"
  - An apple juice blend,
  - A blueberry juice blend,
  - A cranberry juice blend,
  - A grape juice blend,
  - A pineapple juice blend,
  - A plum juice blend,
  - A pomegranate juice blend,
  - A raspberry juice blend?"
- "During the next 3 months, do you think that you, personally, will purchase any bottled drink with a combination or blend of fruit juices or fruit juice flavors?"

- (*IF WILL PURCHASE FRUIT JUICE BLENDS IN THE NEXT 3 MONTHS*) "During the next 3 months, which of the following type or types of juice blends do you think you will purchase?"

  - An apple juice blend,
  - A blueberry juice blend,
  - A cranberry juice blend,
  - A grape juice blend,
  - A pineapple juice blend,
  - A plum juice blend,
  - A pomegranate juice blend,
  - A raspberry juice blend?"

- (*IF HAS OR WILL PURCHASE FRUIT JUICE BLENDS*) "Are you or is someone else mainly responsible for deciding which brand or brands of juice blends to purchase?"

[4] In addition to reading the response categories for this question aloud, interviewers handed survey respondents a sheet with the response categories for them to read. For half the survey respondents, the response categories for this question were read (and listed on the answer sheet) in the order described. For the other half of the survey respondents the categories were read (and listed on the answer sheet) in the following order:

- "Now, I am going to read you a question that has the following three answer choices. Please allow me to read the whole question before answering. After I am done, if you would like me to repeat the question, just ask me. Based on the package, do you think...

  - One, this product does not contain fruit juice,
  - Two, this product does contain fruit juice, or

– Three, do you have no opinion?"

[5] In addition to reading the response categories for this question aloud, interviewers handed survey respondents a sheet with the response categories for them to read. For half the survey respondents, the response categories for this question were read (and listed on the answer sheet) in the order described. For the other half of survey respondents the categories were read (and listed on the answer sheet) in the following order:

- "Now, I am going to read you another question that has three answer choices. Once again, if you would like me to repeat the question, just ask me. Do you think...
  - One, this package does not communicate the type or types of fruit juice it mainly contains,
  - Two, this package does communicate the type or types of fruit juice it mainly contains, or
  - Three, do you have no opinion?"

[6] Altogether 364 eligible adults were reached by telephone within a week or so after they were interviewed at the mall for validation purposes. Of these, 363 (99%) confirmed their participation in the survey. One adult did not confirm her participation in the mall survey (this adult was interviewed for the "control" group). This adult signed the questionnaire and a receipt list and provided her telephone number when interviewed for the mall survey. Although we believe this adult did participate in the mall survey, because she did not confirm her participation her questionnaire was not included in the data analyses. Had her questionnaire been included in the analyses, the survey results would have been virtually identical.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

POM WONDERFUL LLC,
a Delaware limited liability company,
Plaintiff,

v.

THE COCA COLA COMPANY,
a Delaware corporation; and DOES 1-10,
Defendants.

Case No. CV-08-06237 SJO (FMOx)
Judge: Honorable S. James Otero
Date: January 25, 2010
Time: 10:00a.m.
Room: 880

DECLARATION OF DR. RAN KIVETZ IN SUPPORT OF DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

DECLARATION OF DR. RAN KIVETZ, Ph.D.

I, RAN KIVETZ, declare under penalty of perjury as follows:

1. I am the Philip H. Geier Jr. Professor of Marketing at Columbia University Business School. I hold a Ph.D. in Business from Stanford University, Graduate School of Business, a Master's degree in Psychology (M.A.) from Stanford University Psychology Department, and a Bachelor's degree from Tel Aviv University with majors in Economics and Psychology.

2. My fields of expertise are consumer behavior, marketing management, survey methods, human

judgment and decision making, consumer and sales incentives, and marketing high-technology. Over the course of my career, I have conducted, supervised, or evaluated hundreds of marketing research surveys, including many related to consumer behavior and decision-making, sales promotions, marketing strategies, branding, and advertising-related issues.

3. I was asked by counsel for The Coca Cola Company ("TCCC") to review and evaluate the consumer perception survey conducted by Dr. Deborah Jay (the "Jay Survey") on behalf of POM Wonderful LLC ("Pom"). In my professional opinion, the Jay Survey suffers from numerous, fundamental flaws that render the survey's findings unreliable. The Jay Survey does not provide any evidence that the packaging, or any other advertising or promotions for the "Minute Maid Enhanced Pomegranate Blueberry Flavored Blend of 5 Juices" is likely to mislead consumers.

4. If called upon to testify at trial, I am prepared and do intend to offer testimony consistent with the opinions set forth in the two expert reports, dated December 30, 2009 and January 6, 2010, that I have submitted in connection with this matter. Attached hereto as Exhibit A is a true and correct copy of my December 30, 2009 report setting forth my opinions regarding the Jay Survey.

I declare under penalty of perjury under the law of the United States that the foregoing facts are true and correct.

Executed this 15th day of January 2010 in New York, New York.

/s/ R. Kivetz
Dr. Ran Kivetz, Ph.D.

EXHIBIT A

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

POM WONDERFUL LLC,
a Delaware limited liability company,
Plaintiff,

v.

THE COCA COLA COMPANY,
a Delaware corporation; and DOES 1-10, inclusive,
Defendants.

Case No. CV-08-06237 SJO (FMOx)
December 2009

EXPERT REPORT OF RAN KIVETZ

BACKGROUND AND QUALIFICATIONS

1. I am the Philip H. Geier Jr. Professor of Marketing at Columbia University Business School. A copy of my curriculum vitae, which includes a complete list of my publications, is attached as Exhibit A.

2. I hold a Ph.D. in Business from Stanford University, Graduate School of Business, a Master's degree in Psychology (M.A.) from Stanford University Psychology Department, and a Bachelor's degree from Tel Aviv University with majors in Economics and Psychology.

3. My field of expertise is consumer behavior, marketing management, survey methods, human

judgment and decision making, consumer and sales incentives, and marketing high-technology. Most of my research has focused on buyers' purchase behavior; survey design; the effect of product characteristics (such as brand, features, quality, price), the competitive context, and marketing activities (such as promotions, incentives, loyalty programs) on buying decisions; and marketing high-technology.

4. I have received several awards and nominations, including (a) being rated as the third most prolific scholar in the leading marketing journals during 1982-2006,[1] (b) the "Ferber Award" from the Association for Consumer Research, which is the largest association of consumer researchers in the world, (c) the Early Contribution Award from the Society of Consumer Psychology (the premier association of consumer psychologists in the world), (d) three finalist nominations, for the 2009, 2007, and 2005 O'Dell Award, given to the Journal of Marketing Research (the major journal on marketing research issues) article that has had the greatest impact on the marketing field in the previous five years, (e) two finalist nominations for the 2007 and the 2005 Paul Green Award, given to the Journal of Marketing Research article published in the prior year that "demonstrates the most potential to contribute significantly to the practice of marketing research and research in marketing", and (f) a finalist nomination for the award for the Best Article published in the Journal of Consumer Research between 2002 and 2005.

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[1] Seggie, Steven H. and David A. Griffith (2009), "What Does It Take to Get Promoted in Marketing Academia? Understanding Exceptional Publication Productivity in the Leading Marketing Journals," *Journal of Marketing*, 73 (January), 122-132.

5. At Columbia University I have taught MBA and Executive MBA courses on Marketing Strategy and on High-Technology Marketing and Entrepreneurship, covering such topics as developing marketing strategies, customer segmentation, customer acquisition and retention, competitive strategies, branding, pricing, advertising, sales promotions, and buyer behavior. In addition to teaching MBA and Executive MBA courses, I have guided and supervised numerous MBA student teams in their work on company and industry projects dealing with a variety of markets.

6. I have taught several doctoral courses. One doctoral course examines human judgment and decision making and its application to marketing science. It focuses on understanding, predicting, and quantitatively modeling different phenomena and biases in judgment and decision making. A second doctoral course that I have taught deals with consumer behavior, covering such topics as the processes underlying choices and judgments, influences on purchase decisions, attitudes, and persuasion. Both of these courses focus on modeling the various stages involved in a research project, including defining the problem to be investigated, selecting and developing the research approach, data collection and analysis, and deriving conclusions. I also taught in various executive education programs, including a program for marketing managers in high technology companies and a program for marketing managers in pharmaceuticals.

7. I have conducted, supervised, or evaluated hundreds of marketing research surveys, including many related to consumer behavior and decision-making, sales promotions, marketing strategies, branding, trademark, and advertising-related issues. I serve on five editorial boards, including leading journals such

as the *Journal of Marketing Research* and the *Journal of Consumer Psychology*. I have served as a Guest Editor for the *Journal of Marketing Research* and as an Associate Editor for *Marketing Science* and *Management Science*. I am also a frequent reviewer of articles submitted to journals in other fields, such as psychology, decision making, and economics. I received the Outstanding Reviewer Award from the *Journal of Consumer Research*. As a reviewer, I am asked to evaluate the research of scholars wishing to publish their articles in leading scholarly journals. I have also worked as a consultant for companies and organizations on a variety of strategy, marketing, consumer behavior and perception, promotions and advertising, and incentives topics. Additionally, I have served as an expert in litigations involving various marketing and buyer behavior issues, deceptive advertising, market surveys, intellectual property, trademark and trade dress related matters, branding, retailing, promotions, and other areas. A list of cases in which I provided sworn testimony during the past four years is included in Exhibit B. I am being compensated at the rate of $550 an hour. My compensation does not depend in any way on the outcome of this litigation.

8. I was asked by counsel for The Coca Cola Company ("TCCC") to review and evaluate the consumer perception survey conducted by Dr. Deborah Jay (the "Jay Survey") on behalf of POM Wonderful LLC ("POM").

9. I reserve the right to supplement my testimony and this Expert Report in response to any further information provided by the parties, and/or in light of additional documents or testimony brought forth through the discovery in this case, at trial, or other-

wise, which may be brought to my attention after the date of my signature below.

10. Any, and all, of the opinions expressed herein are held to a reasonable degree of professional certainty. The information on which I relied consists of the type of information that is reasonably relied upon in my field of expertise. Documents that I relied on in connection with the preparation of this report are listed in Exhibit C.

INTRODUCTION

11. According to Dr. Jay's Survey Report (p. 1), she was retained by POM to conduct a survey "to determine whether juice blend purchasers are likely to mistakenly believe that the *main* ingredients in Minute Maid® Pomegranate Blueberry juice blend are pomegranate and blueberry juice (and not other types of fruit juice) and, if so, whether this is due to the packaging (the words 'Pomegranate Blueberry' on the front of the bottle and the inclusion of 'Pomegranate Blueberry' in the product name on the back of the bottles)."[2] To achieve this stated objective, Dr. Jay should have addressed several issues when designing the survey and analyzing the results. These issues include, but are not limited to, the use of appropriate, non-leading open-ended questions, the choice of a proper control version for the allegedly deceptive package (or, more generally, for the survey test version), and the complete coding of verbatim responses. In the remainder of my report, I

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[2] It is noteworthy that, on the label of the product packaging at issue, the words "Pomegranate Blueberry Flavored Blend of 5 Juices" are printed, rather than "Pomegranate Blueberry juice blend." In this Expert Report, I will refer to the product at issue as "the Juice," following the Court's preferred phrasing.

evaluate in detail the Jay Survey by addressing the following three main questions:

a. Did the Jay Survey use proper questions and procedures?

b. Did the Jay Survey include appropriate controls?

c. Did the Jay Survey results provide evidence of consumer deception?

DID THE JAY SURVEY USE PROPER QUESTIONS AND PROCEDURES?

12. It is well-accepted that, while a proper survey can provide useful, reliable information, the results of a survey are often largely determined by its methodology. For example, as I have shown in my own research,[3] the choice of methodology can determine whether the survey will demonstrate a significant consumer preference for one alternative or another, making it essential to use the most suitable survey method. Indeed, there is little doubt that, by choosing a biased, seriously flawed methodology, one can create "evidence" of consumer deception or lack thereof. In particular, a survey's questions, controls, and stimuli are all critical determinants of the survey's findings.

13. At the beginning of the Jay Survey, respondents received the following instruction (Q4): "Please look at this product the way you normally do when you shop for beverages. Take as long as you like and tell

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[3] See, e.g., R. Kivetz and I. Simonson (2002), "Self Control for the Righteous: Toward a Theory of Pre-Commitment to Indulgence," *Journal of Consumer Research*, 29 (2), (September), 199-217. This article was a finalist for the award for the Best Article published in the *Journal of Consumer Research* (the major journal on consumer behavior) between 2002 and 2005.

me when you are finished." It is my understanding that the bottle was left in front of respondents for the remainder of the survey, and that respondents could inspect the bottle at any time during the survey (the Jay Survey does not explicitly clarify this point). As I subsequently explain, the fact that respondents could evaluate the bottle while answering any of the survey questions exacerbated the Jay Survey's fatal flaws.

14. After the introduction of the Jay Survey, respondents were read the first question, which assessed their perception of the package's main message/s (Q6a): "What message or messages does this package mainly communicate to you about this product?" A subsequent probing question (Q6b), which was not limited to the main message/s, asked: "Anything else?" In both questions, participants' verbatim responses were recorded by the interviewer. While Q6a and Q6b did not suffer from the major flaws of the survey's subsequent questions, analysis of the verbatim responses to Q6ab indicates that, in both the Test and Control group, few respondents perceived the messages of the package to communicate pomegranate or blueberry juice (see Jay Survey Report, Table 4) or any sort of benefit associated with pomegranate/blueberry juice (e.g., antioxidants). Instead, the verbatim responses to Q6ab indicated that the overwhelmingly predominant takeaways from the bottle package were health claims specifically related to the Juice at issue (e.g., "contains Omega-3/DHA," "nourishes the brain") and completely unrelated to pomegranate/blueberry juice or to the POM Wonderful product.

15. Following Q6b, respondents were asked a close-ended, filter question (Q7) that read: "Based on the package, do you think ... " This close-ended question included three response options that were read to

respondents (the order of the first and second options was appropriately rotated across respondents):

- "One, This product does contain fruit juice
- Two, This product does not contain fruit juice
- Three, Do you have no opinion?"

16. Those respondents who answered that "This product does contain fruit juice" to Q7 were then asked (Q8): "Based on the package, what type or types of fruit juice do you think this product contains?" Next, these respondents were asked (Q9a): "What about the package makes you think this product contains the type or types of fruit juice you mentioned?" A subsequent probing question (Q9b) asked: "Anything else?" In Q8 through Q9b, participants' verbatim responses were recorded.

17. Based upon respondents' verbatim responses to Q8, Dr. Jay found that 14% of survey respondents in the Test group as compared to 1% in the Control group identified pomegranate and blueberry juice and not other types of fruit juice as the types of juice in the product at issue (see Jay Survey Report, Table 6). However, this 13% (net of control) is necessarily inflated because Dr. Jay deviated from standard survey practice, and from her own practice in others parts of the Jay Survey, by failing to ask a follow-up probing question to determine whether respondents perceived that the product contained any other type or types of fruit juice. More specifically, given that Q8's intention was to examine the types of fruit juice that respondents believed were contained in the product, this question should have been followed by a standard probing question regarding any other fruit juices that respondents may have thought the product contains. Because the

Jay Survey failed to ask this standard probing question, participants' responses to Q8 were highly likely to be incomplete and omit other type/s of fruit juice that the respondent perceived the product to contain. Dr. Jay's decision to omit the probing question after Q8 (and after Q11, as discussed later)—but to include a probing question after all other open-ended questions—is particularly puzzling given that her stated objective was "to determine whether juice blend purchasers are likely to mistakenly believe that the *main* ingredients in Minute Maid® Pomegranate Blueberry juice blend are pomegranate and blueberry juice (and not other types of fruit juice) ... " (underlining added).

18. Importantly, Q7 through Q9b, as well as all of the survey's remaining questions (Q10-Q12b) only asked about the type or types of fruit juice contained in the product. The Jay Survey did not ask about (or give respondents an opportunity to mention) the type or types of flavors as opposed to fruit juices communicated by the package. This was a fundamental flaw because the distinction between types of fruit juice and flavors lies at the heart of this case. It is my understanding that, whereas POM alleges that the package causes consumers to mistakenly believe that the Juice predominantly consists of pomegranate and blueberry fruit juices, the defendant argues that the package communicates that the Juice contains pomegranate and blueberry flavor as well as a blend of five fruit juices. Unfortunately, the Jay Survey does not provide any relevant information or results that would allow us to distinguish between the parties' positions on this critical issue. By framing the questions exclusively in terms of fruit juice, the Jay Survey questions (Q7-Q12b) gave respondents no other outlet to mention their impressions of fruit flavor or flavors as opposed to

the type or types of fruit juice in the product at issue. This assuredly biased the Jay Survey results, because it is well known that respondents tend to avoid "no opinion" answers.[4] It is very likely that some respondents who mentioned pomegranate and/or blueberry in response to Q7 through Q12b were merely expressing their understanding that the Juice contains pomegranate and/or blueberry flavors. The Jay Survey should have included explanatory text and/or additional questions to help determine whether respondents who mentioned pomegranate and/or blueberry appreciated the difference between flavor and type of fruit juice.

19. It is my professional opinion that it is likely that the results obtained from Q7-Q12B would have been similar if these questions asked about flavor rather than fruit juice. Consumers who perceived the package to communicate messages about the flavor/s of the Juice were led, and confused by, the Jay Survey into listing the perceived flavor as a "type of fruit juice." Unfortunately, by leading respondents toward "fruit juice" and away from "flavor," the Jay Survey does not allow us to discern the proportion of respondents perceiving that the package communicates certain types of fruit juice from the proportion of respondents perceiving that the package communicates certain flavors. Relatedly, analysis by a research assistant of the verbatim responses to Q8 and Q11 indicates that the vast majority of respondents did not differentiate in their answers between "fruit juice" and "flavor," but rather simply answered Q8 and Q11 by naming a fruit or fruits (Respondents # 01001: "Pomegranate and blueberry, apple,

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[4] Respondents typically want to be perceived as helpful and knowledgeable, and therefore, they tend to avoid "no opinion" responses and try instead to select the "right" answer.

cherry plus grapefruit;" Respondents # 01002: Apple, grape, I did not see anything—pineapple, I guess"). That is, respondents' answers themselves are not directly indicative of whether respondents perceived a fruit juice or a fruit flavor.

20. The fact that the Jay Survey led respondents toward "fruit juice" and away from "flavor," is particularly problematic for the last set of questions (Q10-Q12b) regarding the "type or types of fruit juice" that the product ostensibly "mainly contains." These questions were the ones on which Dr. Jay relied in reaching her conclusion "that a substantial proportion of potential purchasers of pomegranate and blueberry juice blends are likely to mistakenly believe that Minute Maid® Pomegranate Blueberry juice blend *mainly* contains pomegranate and blueberry juice (and no other types of fruit juice) due to the packaging (the words 'pomegranate blueberry' on the front of the bottle and in the product name on the back of the bottle)" (Jay Survey Report, p. 28). Contrary to Dr. Jay's conclusion, given that there is no way to determine whether respondents' answers to Q10 through Q12b referred to their perceptions of "fruit juice" or rather their perceptions of "flavor," the "results" obtained from these questions cannot be relied upon to reach any valid conclusions.

21. Question 10 was a close-ended filter question that read: "Do you think ... " and included three response options that were read to respondents (the order of the first and second options was appropriately rotated across respondents): ·

- "One, This package <u>does</u> communicate the type or types of fruit juice it <u>mainly</u> contains

- Two, This package does not communicate the type or types of fruit juice it mainly contains
- Three, Do you have no opinion?"

Those respondents who answered Q10 by selecting the option "This package does communicate the type or types of fruit juice it mainly contains" were then asked (Q11): "What types or types of fruit juice does this product mainly contain?" Next, these respondents were asked (Q12a): "What about the package makes you think this product mainly contains the type or types of fruit juice you mentioned?" A subsequent probing question (Q12b) asked: "Anything else?" Questions 11 through 12b were open-ended and participants' verbatim responses were recorded.

22. Questions 10 through 12b suffered from multiple flaws (some of which were fatal), which render the data from these questions unreliable and invalid. First, respondents' tendency to provide "helpful" answers and avoid "no opinion" responses led to an inflated rate of affirmative responses to Q10, which as explained below, was highly suggestive and leading. Second, as explained earlier, Q10 through Q12b (as well as the preceding Q8-Q9b) led respondents to provide answers that were interpreted by Dr. Jay as indicative of perceptions of fruit juice/s that the "product mainly contain[s]," whereas in actuality, respondents may very well have perceived (and meant to refer to) flavor/s.

23. Third, Q10 was a highly leading, suggestive, and biased close-ended question. Consider again the first two response options:

- "One, This package does communicate the type or types of fruit juice it mainly contains

- Two, This package does not communicate the type or types of fruit juice it mainly contains".

These response options insinuated that the product did in fact contain a "main type or types of fruit juice" and that the only relevant question was whether the package communicated the identity of that "main type or types of fruit juice." However, a highly relevant and unanswered question in this case is whether or not consumers in fact do perceive that the product contains a main type of fruit juice. Contrary to Q10's suggestion that the product does contain a main type of fruit juice, it is quite possible that consumers in the real marketplace perceive the product to contain a blend of five fruit juices, without even considering the proportions of these juices or perceiving any juice as the main ingredient. Of course, consumers who encounter the Juice and its advertising in the marketplace are not exposed to the Jay Survey and any leading questions like Q10-Q12 that insinuate that the Juice does contain a main type of fruit juice.

24. Indeed, the results pertaining to Q10 support the notion that this question was highly leading and biased. In both the Test and Control groups an overwhelming majority of respondents answered that "This package does communicate the type or types of fruit juice it mainly contains" (88% and 82%, respectively). The fact that respondents in the Control group were as likely as respondents in the Test group to answer Q10 affirmatively—despite that fact that the words "Pomegranate Blueberry" were covered with redacting tape on the control package (and no other fruit juice or flavor was written on the control package)—provides further strong evidence that Q10 was highly leading and biased.

25. Instead of the leading Q10, Dr. Jay should have used a filter question that assesses whether or not consumers do in fact perceive that the package communicates that the Juice contains a main type of fruit juice. Such a question would avoid biasing the results, as the Jay Survey did through presupposition that the Juice does contain a main type of fruit juice.

26. Research on conversational norms[5] (i.e., how respondents interpret and respond to information) and order effects[6] (i.e., how one question influences responses to subsequent questions) indicates that the bias in Q10 likely influenced respondents' answers to all of the subsequent questions. That is, a great deal of prior research indicates that, when answering the questions that followed Q10, respondents were likely to assume that the product does contain a main type or types of fruit juice. Such respondents, for example, would be "forced" to search for plausible "main" type/s of fruit juice and their indications on the package in order to answer Q11 and Q12. It is noteworthy that order effects in survey research have been documented extensively. They have been shown to be especially pronounced under conditions like those that existed in the Jay Survey, namely when the respondents are aware of the preceding question when answering the subsequent

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[5] See, for example, H. P. Grice, "Logic and Conversation," in P. Cole and J. Morgan (eds.), *Syntax and Semantics 3: Speech Acts*, pp. 41-58, Academic Press (1975).

[6] See, for example, F. Strack, "Order Effects in Survey Research: Activation and Information Functions of Preceding Questions," in N. Schwarz and S. Sudman (Eds.), *Context Effects on Social and Psychological Research*, New York: Springer-Verlag (1992).

questions, and when respondents perceive the questions as related.[7]

27. Once respondents were led to answer Q10 affirmatively and to adopt the notion that the Juice does contain a main type of fruit juice/s, their subsequent answers to Q11 and Q12 were biased and determined by this presupposition. In Q11, respondents understood that their task was to "search" the package for a plausible answer regarding what type or types of fruit juice the product could mainly contain. That is, Q11 suffered from a severe demand effect, whereby survey respondents use cues provided by the survey procedure and questions to figure out the purpose of the study and the "correct" answers to the questions they are asked.[8] The respondents then tend to provide (what they perceive as) the correct answers, to make sure that the results "come out right."

28. The results of Q11 were also biased by the fact that, after respondents were asked to identify the types of fruit juice that the product mainly contained, they were not asked a standard probing question to determine whether the package conveyed that the product contained any other main types of fruit juice. More specifically, according to Dr. Jay, the main purpose of her survey was to determine whether respondents misperceived the Juice to contain mainly pomegranate and blueberry juice, but not other types of fruit juice. Relatedly, the Jay Survey Report's main conclusion (p.

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[7] F. Strack (1992).

[8] See, e.g., M. Orne (1962), "On the Social Psychology of the Psychological Experiment," *American Psychologist*, 17, 776-783; W. Darley and J. Lim (1993), "Demand Artifacts in Consumer Research: An Alternative Perspective," *Journal of Consumer Research*, 20 (December), 489-95.

28) was "that a substantial proportion of potential purchasers of pomegranate and blueberry juice blends are likely to mistakenly believe that Minute Maid® Pomegranate Blueberry juice blend *mainly* contains pomegranate and blueberry juice (and no other types of fruit juice) ... " (underlining added). Thus, to be able to investigate the main research question of her survey and to reach the aforementioned conclusion, Dr. Jay should have included probing questions after Q11 regarding any other fruit juices that respondents might have believed the Juice to "mainly contain." By avoiding such follow-up probing questions, the Jay Survey left unanswered the main issue it set out to investigate and did not merit Dr. Jay's conclusion.

29. The biases and demand effect induced by the leading questions of the Jay Survey were exacerbated by the fact that the respondents could re-examine the bottle throughout the entire interview.[9] More specifically, Q11 was essentially a reading or "intelligence" test in which respondents had to figure out which part/s of the package contained the "desired" answer to Q11. In the Test group, respondents could quickly conclude their search for the "correct" answer by reading the front label of the bottle, which displayed the words "Pomegranate Blueberry." Of course, in the real marketplace consumers are not "guided" by leading questions and demand effects, and thus consumers' decision-making and judgment are quite different from the reported perceptions of the Jay Survey participants. Given the multiple fatal flaws and biases in the Jay

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[9] It is noteworthy that the fact that respondents could reexamine the bottle at any stage of the Jay Survey biased the results pertaining to all of the questions and not just Q11.

Survey's questions and procedure, the "findings" based on Q10 and Q11 are completely invalid and unreliable.

30. Relatedly, the results pertaining to the subsequent Q12a and Q12b are obvious and uninformative. Once Test group respondents are led in Q10 and Q11 to identify pomegranate and blueberry as the types of fruit juice that the product "mainly contains," respondents obviously allude to the words "pomegranate blueberry" on the bottle when responding to a question that reads (Q12a): "What about the package makes you think this product mainly contains the type or types of fruit juice you mentioned?" Further, Q12a itself is leading and circular, because it focuses respondents on the package instead of asking a neutral, non-leading question, such as "What makes you think that this product mainly contains the type or types of fruit juice you mentioned?"

31. The information reviewed in the preceding paragraphs indicates that the Jay Survey used a highly flawed and biased set of questions and procedure. Thus, a proper control was absolutely essential in order to "net" out the effects of these systematic biases. As explained next, the Jay Survey failed to use a proper control.

DID THE JAY SURVEY INCLUDE APPROPRIATE CONTROLS?

32. A fundamental principle of survey design is that a study intended to evaluate whether an advertisement, product packaging, or any other marketing communication creates misperceptions (and other such cause-effect experiments) must include a proper con-

trol.[10] A control is used to measure the extent of "noise" or "error" in the survey. That is, an estimate of the net effect of an ad or package on consumer misperceptions can be derived by subtracting the control estimate from the corresponding estimate in the "test" question or group, which addresses or is exposed to the allegedly deceptive ad/package. Without a proper control, there is no benchmark for evaluating whether an estimate derived from the survey is significant and informative or whether it merely reflects "noise." Such "noise" can arise from guessing behavior, respondents' prior knowledge, experiences, and attitudes, and/or any flaws inherent in the survey's questions and methodology. Thus, in a survey intended to test for consumer confusion, the choice of a proper control is absolutely critical.

33. An effective control condition or control stimulus (e.g., a product advertisement or package) needs to be as similar as possible to the advertisement or package at issue, correct for the allegedly misleading statement, and be commercially viable. For example, if the package at issue makes a certain representation about fruit juices and/or flavors, then the control package must equally contain a representation about fruit juices and/or flavors, but a representation that is not allegedly deceptive. Such equivalence between the test and control conditions is important in order to ensure that any differences in participants' responses to the test versus the control stimuli arise only due to the specific element (e.g., statement or claim) at issue rather than due to factors that are irrelevant to the case.

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[10] S. Diamond, *Reference Guide on Survey Research*, in *Reference Manual on Scientific Evidence*, (Federal Judicial Center ed., 2000), 256-260.

34. In the present case, given that the package at issue contained a particular statement (i.e., "Pomegranate Blueberry Flavored Blend of 5 Juices") that was alleged to be confusing, the control package should have contained a revised statement, with all the other elements in the package kept the same. For example, Dr. Jay could have simply replaced the phrase "Pomegranate Blueberry Flavored Blend of 5 Juices" with another phrase, such as "Pomegranate Blueberry Flavored Blend of Apple, Grape, and Other Juices" or "A Blend of Apple, Grape, and Other Juices with Pomegranate Blueberry Flavoring." Such control statements clearly do not communicate that the Juice mainly contains pomegranate and blueberry fruit juice and are obviously not deceptive, but they still convey messages about fruit juices and flavors in the Juice. Again, the control package should have been as similar as possible to the test version, except for changing the particular phrase at issue (a similar revision could have been made in the label on the back ofthe bottle).

35. In actuality, the control package used by Dr. Jay to calculate the net effect of the allegedly misleading package was far from equivalent to the package used in the Test group, in terms of its (a) use of redacting tape to conceal the identity of the Juice's flavors instead of creating an alternative label; (b) failure to indicate any specific flavor/s; and (c) lack of commercial viability (or deviation from common marketplace conditions). Whereas the (original) package in the Test group included the phrase "Pomegranate Blueberry Flavored Blend of 5 Juices," the (revised) package in the Control group concealed the words "Pomegranate Blueberry" by using redacting tape and only displayed the remainder of the phrase "Flavored Blend of 5 Juices." The same flawed approach—of using a redacting

tape to hide the Juice's flavors instead of creating an alternative label—was applied to the back of the bottle. In particular, the words "Minute Maid® Pomegranate Blueberry is" were covered using the redacting tape and the remainder of the phrase "Made with a Blend of Apple, Grape, Pomegranate, Blueberry and Raspberry Juices from Concentrate and Other Ingredients" was displayed. Thus, it was completely transparent to respondents that redacting tape was used to conceal portions of the front and back labels of the control package. As discussed next, this approach resulted in a fatally flawed control stimulus.

36. First, contrary to the test condition, the control condition presented respondents with a package that was revised using redacting tape, which was visible to respondents. The use of redacting tape clearly indicated to respondents that the bottle was manipulated. Given that respondents were aware that they were participating in a study, such an obvious manipulation directed their attention and suspicion toward any changes made to the package, gave away the fact that the bottle was in fact altered for purposes of the survey, and evoked demand effects as to the purpose of the survey and the research questions. More specifically, combined with the survey's leading questions (Q7-Q12), which focused respondents on fruit juice/s, the artificial and obtrusive redacting tape signaled to respondents that their task was to decipher the obscured information regarding the Juice's (main) ingredient/s. Thus, given that the bottle was still available for inspection, respondents' perceived "task" was to find the "solution" or "right answer" (e.g., to Q8 and Q11) using other information on the front and back of the bottle. The survey, therefore, became more of an "intelligence" and reading test than a perception survey.

37. Second, the control package failed to provide any information regarding the Juice's flavor. Thus, the control package represents a highly unrealistic stimulus, which is not commercially viable (i.e., real bottles of juice almost always provide information regarding the product's flavor). As mentioned earlier, it is highly puzzling that Dr. Jay chose to eliminate all mentions of the product's flavor instead of (appropriately) revising the contested phrase in such a way that it still communicates textual information about the product's fruit flavor/s and/or juice/s, but without making any allegedly misleading representation. For example, the allegedly deceptive statement could have been revised from "Pomegranate Blueberry Flavored Blend of 5 Juices" to "Pomegranate Blueberry Flavored Blend of Apple, Grape, and Other Juices" or "A Blend of Apple, Grape, and Other Juices with Pomegranate Blueberry Flavoring."

38. By removing from the control package any mention of the product's pomegranate and blueberry flavor, Dr. Jay artificially lowered the level of reported perceptions of pomegranate and/or blueberry juice in the Control group. The use of such a commercially unviable control package, which was far from equivalent to the test package, effectively guaranteed a (biased) result that favors the position of POM. It is important to reiterate that a proper control stimulus would correct for the allegedly misleading statement but still mention the Juice's pomegranate blueberry flavor, thereby retaining the control bottle's commercial viability and equivalence to the test bottle. Among other reasons, such equivalence is important because consumers might be confused about the main types of fruit juice in the product (whether because of their preexisting beliefs or the leading/confusing nature of the survey

itself) even when the package communicates the pomegranate blueberry flavor in a clearly acceptable manner.

39. Thus, had Dr. Jay used a commercially viable control package that mentions the pomegranate blueberry flavor (and asked unbiased non-leading questions), it is likely that the "net deception" effect (calculated by subtracting the control estimate from the test estimate) would fall below the 20% threshold that many courts use as the minimum acceptable level for proof of deception.

40. Third, and relatedly, the artificial use of redacting tape and the lack of any textual information about the product's fruit juice/s and/or flavor/s made the control bottle highly unrealistic and unrepresentative of a commercially viable product. That is, consumers virtually never encounter in the real marketplace a bottle like the Jay Survey's control bottle. As Professor McCarthy points out[11], the survey method should mirror the situation in which the ordinary person encounters the product and should reflect marketplace conditions as closely as possible. This rule has particular significance with respect to the manner of stimuli presentation. Further, one important determinant of the severity of demand effects is the degree to which the manner of presentation in the context of the survey reflects marketplace conditions. Thus, the set of information, stimuli, and products that customers face in a

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[11] 4 J. Thomas McCarthy, McCarthy on Trademarks and Unfair Competition (September 2007) (McCarthy) at §32: 163. While I am not an attorney or an expert on legal matters, I find it useful to refer to legal authorities and prior court decisions to illustrate the types of issues and principles that have come up in connection with the evaluation of perception surveys.

litigation survey should be as similar as possible to what they experience in the actual marketplace. When a survey does not mirror the marketplace conditions, the results have low predictive validity (i.e., they are inaccurate in predicting real consumer perceptions) and the survey does not allow reaching conclusions about the issues being tested. The failure of the control condition to mirror marketplace conditions likely led respondents to behave in a manner that differed from consumer behavior and information processing in the real marketplace and in the Test group. This renders the control condition of the Jay Survey an inappropriate control that does not allow calculating the true "net" deception rate.

41. Overall, it is my professional opinion that the control condition used in the Jay Survey to estimate net deception effects was completely inappropriate and did not correct for the biases and "noise" in the Jay Survey. The Jay Survey used an unrealistic, commercially unviable, and non-equivalent control bottle stimulus. The failure to use a proper control was especially damaging in the current survey due to the multiple inherent flaws of the survey questions and methodology (reviewed earlier). It was therefore critical to use a control that was equivalent to the test stimulus, to account for such "noise" (arising, e.g., from the survey's inherent flaws, respondents' prior beliefs, or conversational norms). The lack of a proper control inflates the purported "confusion" in the Jay Survey and invalidates Dr. Jay's conclusions that the package is misleading.

WHAT, IF ANYTHING, CAN WE LEARN FROM THE RESULTS OF THE JAY SURVEY?

42. Given the multiple flaws in the Jay Survey's methodology, questions, and control stimuli, a question

that naturally arises is what, if anything, can we learn from the results of the survey. In this section, I review some informative findings from Q6 and Q8, as well as report relevant re-coding of the verbatim responses to Q6.

43. As detailed earlier, Q10, Q11, and Q12 were extremely biased and leading questions, and as such were completely inappropriate for testing consumers' spontaneous perceptions. Thus, I will not assess in detail the results pertaining to these fatally flawed and uninformative questions.

44. Given that Q6a and Q6b did not suffer from the major flaws of the survey's subsequent questions, it is worthwhile to carefully evaluate the responses to these questions. Such an analysis reveals that, in both the Test and Control groups, very few respondents perceived the message/s of the package to communicate pomegranate or blueberry juice (9% vs. 3%, respectively). Additionally, the 6% difference between the Test and Control groups in takeaways of pomegranate or blueberry juice is unsubstantial and meaningless. This indicates that the reference to pomegranate and blueberry in the Juice's name was <u>not</u> salient to respondents.

45. Importantly, the verbatim responses to Q6ab indicated that the overwhelmingly predominant takeaways from the package—in both the Test and Control groups—were benefits specifically tied to the Juice at issue, such as "That it nourishes your brain" (Respondent # 01005), "Juice that has a lot of Omega-3" (Respondent # 01003), "It's enhanced Minute Maid juice. That's good for my brain" (Respondent # 01052), "The manufacturer—Minute Maid was the first thing I noticed" (Respondent # 02153), and "Lots of fruit juices

and five nutrients. Supports the body and brain" (Respondent # 02001). Table 4 of the Jay Survey indicates that in both the Test and Control groups, 87% of respondents perceived the messages communicated by the package to be related to such benefits as Omega-3/DHA, nourishing the brain, nutrients, and so-forth. These type of messages and benefits are completely unrelated to pomegranate and blueberry juice or to the POM's product. Moreover, the express references to pomegranate and blueberry on the test package do not enhance consumers' overall impressions of the Juice's healthiness or benefits.

46. Given that they Jay Survey was intended to test whether consumers mistakenly believe that the main ingredients in the Juice are pomegranate and blueberry juice, it is surprising that Dr. Jay chose not to report the percent of respondents whose verbatim responses to Q6ab were about benefits that POM claims its pomegranate and blueberry products may provide. Such health benefits are listed on POM's website and also discussed in the report of POM's damages expert, Mr. Anastasi. These pomegranate/blueberry potential hea[l]th benefits relate to antioxidants, free-radicals, oxidative stress, heart disease and increased blood flow to the heart, diabetes, hypertension, premature aging, cancer, prostate health and improved PSA values, erectile dysfunction and increased odds of erection, and atherosclerosis/clogged arteries.

47. To investigate whether respondents perceived the message/s of the package to communicate pomegranate/blueberry-related health benefits, I asked a research assistant to recode the verbatim responses to Q6ab. The research assistant coded verbatim responses that mentioned any of the health benefits listed in Paragraph 46. The results of this re-coding indicate

that (a) antioxidants were mentioned by 4.0% (11/271) of respondents in the Test group versus 2.2% (6/267) of respondents in the Control group;[12] (b) heart disease and increased blood flow to the heart were mentioned by 1.1% (3/271) of test respondents versus 1.5% (4/267) of control respondents; (c) diabetes was mentioned by just one control respondent and no test respondent; and (d) none of the other health benefits listed in Paragraph 60 were mentioned by either test or control respondents. Overall, in both the Test and Control groups, very few respondents perceived the messages of the package to communicate pomegranate/blueberry juice or any sort of benefit supposedly associated with such juice.

48. The results from Q8 indicated that 74% of Test group respondents and 79% of Control group respondents answered that the product contains pomegranate and/or blueberry juice and one or more other types of fruit juice (see Jay Survey Report, Table 6). Thus, the vast majority of both test and control respondents understood that the product contained a blend of multiple juices rather than just pomegranate and/or blueberry only. In fact, had Dr. Jay included the appropriate and standard probing question after Q8, it is highly likely that even a greater percent of respondents would indicate that the product consisted of a blend of multiple juices.

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[12] It is noteworthy that although the back label of the bottle (in both the Test and Control groups) indicated that the beverage contains antioxidants, very few respondents perceived the package to communicate a message of antioxidants; further, this low rate of antioxidant mentions did not differ across the Test and Control groups.

49. The only reliable findings of the Jay Survey provide no support (and actually contradict) POM's allegations this case. In my professional opinion—having conducted, supervised, and evaluated hundreds of academic and litigation surveys that entail such cause-effect experiments—the results of the Jay Survey that Dr. Jay relies upon in concluding that a substantial portion of consumers are likely to be confused by the Juice's name and label were unreliable, unsubstantial, and completely insufficient as scientific evidence.

SUMMARY OF CONCLUSIONS

50. The preceding analyses clearly demonstrate that the Jay Survey employed an inadequate methodology that was inconsistent with fundamental and well-accepted survey principles. My professional opinion is that the Jay Survey is unreliable, mostly irrelevant, and does not provide any evidence that the package at issue misleads consumers. In conclusion, the Jay Survey:

(a) used questions that were highly biased, leading, and generated strong order and demand effects, which in turn led respondents to provide predictable and "correct" answers that were biased in favor of POM's position;

(b) relatedly, failed to use a proper filter question to assess whether or not consumers do in fact believe that the Juice contains any main type or types of fruit juice;

(c) included an inadequate, commercially unviable, and suspicious control package that was far from equivalent to the test package being tested. The fatally flawed control package, which used obtrusive redacting tape and did not mention any flavors, bi-

ased the results in a direction that favored the position of POM and inflated the survey's net "deception" effect;

(d) focused respondents on type/s of fruit juice contained in the product, and failed to clarify whether respondents' reported perceptions referred to types of fruit juice or to the product's flavor/s;

(e) used a flawed interview procedure that allowed respondents to inspect the bottle at any time during the questioning. Combined with the survey's leading, one-sided questions and fatally flawed control, these flaws transformed the survey into a reading and "intelligence" test, with predictable "results"; and

(f) demonstrated that few respondents perceive the message/s of the package to communicate pomegranate/blueberry juice or any benefit associated with pomegranate/blueberry juice. The results also demonstrated that the overwhelmingly predominant takeaways from the package were tied to the specific benefits of the Minute Maid Juice and were completely unrelated to pomegranate/blueberry juice, its potential benefits, or to POM's products.

12/30/2009 /s/ R. Kivetz
Date Dr. Ran Kivetz, Ph.D.

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

POM WONDERFUL LLC,
a Delaware limited liability company,
Plaintiff,

v.

THE COCA COLA COMPANY,
a Delaware corporation; and DOES 1-10, inclusive,
Defendants.

Case No. CV-08-06237 SJO (JLTx)
Judge: Honorable S. James Otero
Date: April 6, 2010
Time: 10:00a.m.
Room: Courtroom 1, Second Floor

DECLARATION OF NANCY TYNDAL IN FURTHER SUPPORT OF DEFENDANT'S MOTION IN LIMINE NO. 4

DECLARATION OF NANCY TYNDAL

I, Nancy Tyndal, declare under penalty of perjury as follows:

1. I am personally familiar with the facts set forth in this declaration. If called as a witness, I would competently testify to the matters stated herein. I submit this declaration in support of The Coca-Cola Company's ("TCCC" or "Minute Maid") motion to exclude evidence of consumer inquiries to Minute Maid.

2. I am Manager, Client Services, at The Coca-Cola Company. In connection with performing my job duties, I am aware of consumer inquiries, comments, and complaints made to Minute Maid with respect to Minute Maid Enhanced Pomegranate Blueberry Flavored Blend of 5 Juices (the "Juice").

3. I testified at deposition on December 10, 2009 as Minute Maid's Rule 30(b)(6) designee about these

consumer inquiries. Attached as Exhibit 1 is a true and correct copy of excerpts from my deposition transcript.

4. Towards the end of my deposition, Minute Maid's counsel asked me whether the Juice and the Minute Maid Enhanced Juice brand received an unusually high number of consumer inquiries relative to other Minute Maid products and other Coca-Cola brands of products. I answered that the number of inquiries received was very small compared to other products and brands. *See* Exh. 1 at pp. 8-9 (Tyndal Dep. Tr. 236:15-237:2).

5. Later in the deposition, Pom's counsel asked me whether there had been any other products that Minute Maid has sold in which more consumers have complained that the name and label on the product is misleading than the Juice. *See* Exh. 1 at p. 10 (Tyndal Dep. Tr 252:6-18). I answered "no" only because I misunderstood the question.

6. I understand that Pom has cited my testimony in stating that the Juice has received a record number of complaints compared to other Minute Maid and Coca-Cola products. I disagree with such statements. In fact, I know that Pom's statements are not accurate.

7. Following my deposition, I again reviewed Minute Maid's record of consumer inquiries regarding the Juice. Since the U.S. launch of the Juice until January 13, 2010, Minute Maid received approximately 2,600 consumer comments regarding the Juice. Less than 1% of the comments, approximately 20 in total, were complaints regarding the Juice's name or labeling.

8. Based upon my 15 years of experience within TCCC's consumer affairs department, I can attest that the number of consumer complaints that Minute Maid

has received regarding the Juice's name and label is very small and comparable to, and in some cases lower than, the number of naming and labeling related complaints that other TCCC products have received.

I declare under penalty of perjury under the laws of the state of Georgia and the United States that the foregoing facts are true and correct.

Executed this 16th day of February 2010 in Atlanta, Georgia.

/s/ Nancy Tyndal
Nancy Tyndal

EXHIBIT 1

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

POM WONDERFUL LLC,
a Delaware limited liability company,
Plaintiff,

vs.

THE COCA COLA COMPANY,
a Delaware corporation; and DOES 1-100,
Defendants.

Case No.: CV08-06237 SJO (JLTx)
December 10, 2009
9:18 a.m.

DEPOSITION OF NANCY TYNDAL

---

* * *

[234]

A. Yes.

MR. SILVERMAN: Objection. Assumes facts not in evidence.

BY MR. TU:

Q. Counsel did not take you through every one of the consumer comments reflected in Exhibit 6, 7 or 8; is that right?

A. Yes.

Q. He took you through a handful that he selected; is that correct?

MR. SILVERMAN: Objection. Facts – assume facts not in evidence. It was certainly more than a handful. A handful is five. We discussed dozens.

BY MR. TU:

Q. Counsel took you through some number less than the total amount of comments that are reflected in Exhibits 6, 7 and 8, is that fair?

A. Yes.

Q. Now, the comments or the transcriptions, the recordings that are reflected here that counsel took you through, do you believe that they broadly represent the [235] nature of the comments received that are reflected in Exhibits 6, 7 and 8?

MR. SILVERMAN: Objection. Vague and ambiguous.

THE WITNESS: No.

BY MR. TU:

Q. And why do you say that, Ms. Tyndal?

A. If we're looking at Exhibit 8 and – which is a larger version than Exhibit 6 with – or 7, I believe, we really received approximately 1,794 contacts in this particular report. A good 200 plus are compliments on this brand. Approximately 1,000 are inquiries about the brand and then the rest are complaints, so a good 10 percent are compliments which is a bit above the norm of what we usually receive on – on compliments when it comes to brands.

Q. Thank you. I'm just going to turn your attention to a few of the pages in Exhibit 8.

A. If I can just add one thing as well –

Q. Sure, you may.

A. – as far as our department is concerned. These particular records probably represent maybe a year or so or a year and a [236] half of documents but on a yearly basis we take about a million consumer inquiries, complaints, complements so – or inquires. We handle approximately a million consumer touches so to speak so . . .

Q. And is that across all of the brands that you service?

A. All of the brands. All of the brands, anything that's related to the company so I would say when you combine your calls, e-mails and letters, easily we reach about a million a year. So on this particular brand it seems like maybe we had close to 900 for a year or so.

Q. And did this particular product within this particular brand receive an unusually high number of consumer touches relative to other brands within the Coca-Cola franchise?

MR. SILVERMAN: Objection. Vague and ambiguous as to both high number of touches and relative.

BY MR. TU:

Q. If you understood the question, you may answer.

A. These number of contacts are very small [237] compared to some of our other brands.

Q. Now, just so I understand, you had said that within the universe of consumer touches reflected in Exhibit 8, you characterized that as I believe a high number of compliments. Is that fair?

A. Yes.

Q. Would you mind turning to the Bates page ending 5002.

MR. SILVERMAN: 5002?

MR. TU: Yes.

THE WITNESS: Yes.

BY MR. TU:

Q. Will you look at the comment that's number 238.

A. Okay. Yes.

Q. It says hello, I'd like to tell you – know that our family is absolutely addicted to the new pomegranate blueberry juice. It's good to find something that the kids love and it's good for them. My only complaint is that when it's not on sale, the cost is over $5 per bottle and we're drinking a lot of it. I'm wondering if you have any coupons to help out.

* * *

[252] why he doesn't eat blueberries nor why he'll drink the particular product because of antioxidants.

BY MR. SILVERMAN:

Q. You said that there's other brands — other products sold by The Coca-Cola Company or Minute Maid that get more contacts I think was the word you used. Right?

A. (Non-verbal response).

Q. Yes?

A. Yes. I'm sorry. Yes.

Q. In your experience have there been any other products that Minute Maid has sold in which more consumers have complained that the name and label on the product is misleading than the pomegranate blueberry product?

A. No.

MR. SILVERMAN: I've gotta – do you gotta change the tape?

THE VIDEO OPERATOR: Yes.

MR. SILVERMAN: Okay. Why don't you change the tape. I'm not quite finished.

THE VIDEO OPERATOR: This is the

* * *

PETITIONER'S BRIEF

No. 12-761

IN THE

Supreme Court of the United States

POM WONDERFUL LLC,

Petitioner,

v.

THE COCA-COLA COMPANY,

Respondent.

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

BRIEF FOR PETITIONER

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QUESTION PRESENTED

Whether the court of appeals erred in holding that a private party cannot bring a Lanham Act claim challenging a product label regulated under the Food, Drug, and Cosmetic Act.

PARTIES TO THE PROCEEDINGS

The case caption contains the names of all parties who were parties in the court of appeals.

RULE 29.6 STATEMENT

Pom Wonderful LLC is directly owned by Pom Wonderful Holdings LLC, which is directly owned by Roll Global LLC and ultimately owned by Stewart and Lynda Resnick as trustees of the Stewart & Lynda Resnick Revocable Trust. No publicly held company holds any interest in the Stewart & Lynda Resnick Revocable Trust.

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IN THE

Supreme Court of the United States

No. 12-761

POM WONDERFUL LLC,

Petitioner,

v.

THE COCA-COLA COMPANY,

Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR PETITIONER

OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-14a) is reported at 679 F.3d 1170. The district court's motion to dismiss orders (Pet. App. 75a-101a) are unreported. The district court's summary judgment order (Pet. App. 21a-73a) is reported at 727 F. Supp. 2d 849.

JURISDICTION

The court of appeals entered judgment on May 17, 2012. The court denied rehearing and rehearing en

banc on August 8, 2012. Pet. App. 15a-16a. On October 31, 2012, Justice Kennedy extended the time within which to file a petition for a writ of certiorari to and including December 21, 2012. The petition was filed on that date and granted on January 10, 2014. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS AND REGULATIONS

The relevant provisions of the Lanham Act, 15 U.S.C. §§ 1051 *et seq.*; the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*; and the Food and Drug Administration's regulations, 21 C.F.R. pts. 101 & 102, are set forth in the Appendix to this brief.

PRELIMINARY STATEMENT

Respondent Coca-Cola has designed its "Pomegranate Blueberry" juice product to mislead consumers. Over 99% of the product is apple and grape juice. The amounts of pomegranate and blueberry juice it contains—0.3% and 0.2% respectively—are so trivial that no consumer could perceive them. Yet every aspect of the product's appearance is tailored to convince consumers that it contains significant amounts of pomegranate and blueberry juice. The words "Pomegranate" and "Blueberry" appear in large font on the front of the bottle, each occupying a single line of the label. These words dwarf the FDA-required disclaimer, "Flavored Blend of 5 Juices," which is set in significantly smaller font on a separate line below the product name. The bottle prominently displays images of a pomegranate and oversized blueberries, which appear, respectively, in front of images of an apple and grapes. The product is colored deep purple to resemble pomegranate and blueberry juice. *See infra* p. 9 (image).

Petitioner Pom Wonderful LLC sells pomegranate juice and pomegranate juice blends that compete with Coca-Cola's product. A consumer survey conducted by Pom showed that consumers are misled in large numbers to believe that Coca-Cola's product actually has substantial amounts of pomegranate and blueberry juice. Having concluded that it was losing sales of its actual pomegranate juice products to Coca-Cola's deceptive product, Pom brought suit under the Lanham Act. An internal Coca-Cola document produced in discovery revealed that Coca-Cola knew its "Pomegranate Blueberry" product posed "a risk from a misleading standpoint as the product has less than 0.5% pomegranate and blueberry juices"—but was "willing to assume the risk."

The Ninth Circuit held that Pom's Lanham Act challenge must be dismissed as a matter of law. It concluded that no matter how misleading Coca-Cola's product is, the Food, Drug, and Cosmetic Act ("FDCA") impliedly bars Pom's suit. The court recognized that no provision of the FDCA precludes Lanham Act actions, and the court did not dispute that Coca-Cola could have complied with the requirements of both statutes. The court further acknowledged that FDA's regulations implementing the FDCA do not address all aspects of Coca-Cola's misleading label and that it was unclear whether Coca-Cola's product in fact complied with the regulations to the extent they applied. The Ninth Circuit nonetheless held that Lanham Act challenges to misleading food labels are impliedly precluded because FDA regulates food labeling under the FDCA. There is no support for that sweeping holding, which would shield a broad range of indisputably misleading statements from challenge, even by competitors directly harmed by those statements.

As a matter of separation of powers, the courts are duty bound to give effect to all federal statutes unless Congress has directed otherwise or the statutes irreconcilably conflict. Here, Congress did not create an exception to the Lanham Act for food labeling claims, and Coca-Cola could easily have complied with both the Lanham Act and the FDCA. Accordingly, the judgment should be reversed.

STATEMENT

A. Statutory And Regulatory Framework

1. The Lanham Act

In 1946 Congress enacted the Lanham Act to make "actionable the deceptive and misleading use of marks"; "protect persons engaged in [interstate] commerce against unfair competition"; and "provide rights and remedies stipulated by treaties and conventions respecting ... unfair competition." Pub. L. No. 79-489, § 45, 60 Stat. 427, 444 (1946) (codified at 15 U.S.C. § 1127) (noting the "intent" of the Act); *see also Dastar Corp.* v. *Twentieth Century Fox Film Corp.*, 539 U.S. 23, 28-29 (2003). Congress intended the Act to secure to a business owner "the good will of his business and protect[] the public against spurious and falsely marked goods." S. Rep. No. 79-1333, at 3 (1946), *reprinted in* 1946 U.S.C.C.A.N. 1274; *see also, e.g., Conte Bros. Automotive, Inc.* v. *Quaker State-Slick 50, Inc.*, 165 F.3d 221, 229 (3d Cir. 1998) (Alito, J.) (Lanham Act "focus[es] ... on anti-competitive conduct in a commercial context.").

The Act protects businesses from unfair competitive acts by providing a private cause of action to a commercial plaintiff that has been harmed by a competitor's false advertising. 15 U.S.C. § 1125(a)(1)(B). As

amended, § 1125(a) imposes liability, in relevant part, on

> any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any ... false or misleading description of fact, or false or misleading representation of fact, which ... (B) ... misrepresents the nature, characteristics, qualities, or geographic origin of his or her ... goods[.]

Id. § 1125(a)(1)(B).[1] The Act thus provides a private remedy to a "commercial plaintiff" whose "commercial interests" have been harmed through false or misleading representations. *Sandoz Pharm. Corp.* v. *Richardson-Vicks, Inc.*, 902 F.2d 222, 230 (3d Cir. 1990).

2. The FDCA

Enacted in 1938 (*see* Pub. L. No. 75-717, 52 Stat. 1040 (1938)), the FDCA regulates (among many other things) the labeling of food and beverages. The statute prohibits the misbranding of "food," 21 U.S.C. § 331,

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[1] Section 1125 has been amended on several occasions since 1946, including when Congress enacted the Trademark Law Revision Act of 1988, Pub. L. No. 100-667, § 132, 102 Stat. 3935, 3946, which redrafted § 1125(a) and largely codified pre-1988 case law. *See* S. Rep. No. 100-515, at 40-41 (1988), *reprinted in* 1988 U.S.C.C.A.N. 5577, 5603-5604; *ALPO Petfoods, Inc.* v. *Ralston Purina Co.*, 913 F.2d 958, 964 n.6 (D.C. Cir. 1990); *see also, e.g.*, Trademark Remedy Clarification Act, Pub. L. No. 102-542, § 3(c), 106 Stat. 3567, 3568 (1992) (adding 15 U.S.C. § 1125(a)(2)); Trademark Amendments Act of 1999, Pub. L. No. 106-43, § 5, 113 Stat. 218, 220 (adding 15 U.S.C. § 1125(a)(3)).

which includes any "article[] used for food or drink for man," *id.* § 321(f). The statute then specifies circumstances in which a food is "deemed to be misbranded." *Id.* § 343. These include instances where "labeling is false or misleading in any particular"; where required information "is not prominently placed thereon with [sufficient] conspicuousness"; and where a label fails to "bear ... the common or usual name of the food." *Id.* § 343(a), (f), (i)(1).

In 1990 Congress amended the FDCA's labeling provisions by enacting the Nutrition Labeling and Education Act ("NLEA"). Pub. L. No. 101-535, 104 Stat. 2353 (1990).[2] Among its reforms, the NLEA required nutritional labeling for most food products and regulated the manner in which food labels characterize the nutrients present in a product and the relationship between those nutrients and health conditions. *See, e.g.*, *id.* §§ 2-3 (codified at 21 U.S.C. § 343(q)-(r)).

Whereas the Lanham Act is intended to protect against unfair competition, the FDCA's misbranding provisions seek principally to protect public health and

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[2] In addition to enacting the NLEA in 1990, Congress has amended the FDCA's food misbranding provisions on several other occasions since 1938. *See, e.g.*, Color Additive Amendments of 1960, Pub. L. No. 86-618, § 102(a)(3), 74 Stat. 397, 398 (adding 21 U.S.C. § 343(m)); Dietary Supplement Health and Education Act of 1994, Pub. L. No. 103-417, § 7(a), 108 Stat. 4325, 4329-4330 (adding 21 U.S.C. § 343(s)); Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, § 308(b), 116 Stat. 594, 672-673 (adding 21 U.S.C. § 343(v)); Food Allergen Labeling and Consumer Protection Act of 2004, Pub. L. No. 108-282, tit. 2, § 203(a), 118 Stat. 891, 906-908 (adding 21 U.S.C. § 343(w)-(x)).

safety. *See 62 Cases of Jam* v. *United States*, 340 U.S. 593, 596 (1951); *Holk* v. *Snapple Beverage Corp.*, 575 F.3d 329, 331-332 (3d Cir. 2009). Presumably for that reason, the FDCA does not create a private cause of action to remedy noncompliance; the statute permits only government enforcement. *See* 21 U.S.C. § 337(a). In contrast to the Lanham Act's civil liability provisions, violations of the FDCA's prohibition on misbranding of food may be criminally prosecuted. *See id.* § 333(a).

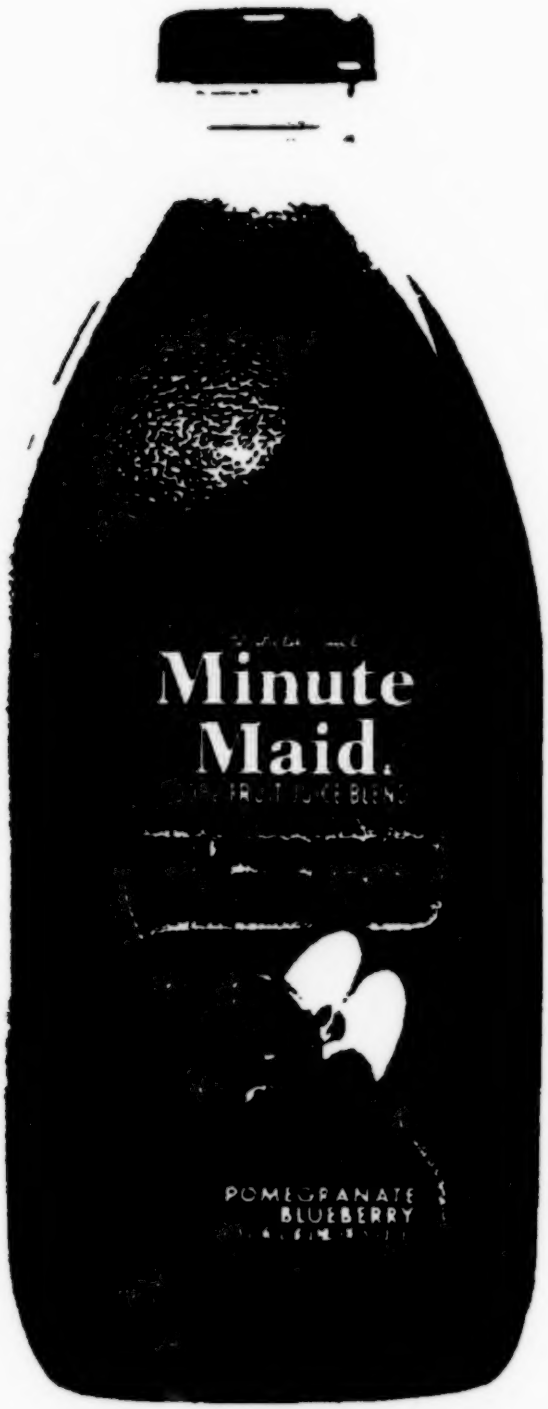
FDA has promulgated regulations that relate to various aspects of food labeling, including labeling of juice products. *See, e.g.*, 21 C.F.R. § 101.18(b) (misbranding of food by selective inclusion of ingredients in a product's name), § 102.5(b) (naming of food products where characterizing ingredients bear on price or consumer acceptance), § 102.33(b)-(d) (naming of beverages containing multiple juices). *See infra* pp. 22-24, 47-52.

Both as originally enacted and as amended by the NLEA, the FDCA's misbranding provisions do not purport to displace other provisions of federal law. By contrast, the NLEA does specifically address the FDCA's effect on state laws. *See* Pub. L. No. 101-535, § 6 (21 U.S.C. § 343-1 & note). The statute narrowly displaces only those state laws that purport to impose labeling requirements "of the type" imposed by certain enumerated provisions of the FDCA that are not "identical" to the requirements of those provisions. 21 U.S.C. § 343-1(a)(2), (3). In a parallel saving clause, Congress specified that no further preemption of state law should be implied from the NLEA's preemption provision. *See* Pub. L. No. 101-535, § 6(c)(1) (21 U.S.C. § 343-1 note).

B. Coca-Cola's Willful Deception

This is a classic Lanham Act false advertising case. Pom and Coca-Cola compete directly in the market for pomegranate juices. JA 25a, 27a-28a. Pom is the largest grower of pomegranates and distributor of pomegranate juice in the United States. JA 23a. It has been selling and marketing its juice products since 2002. *Id.* Through its POM WONDERFUL® brand, Pom produces, markets, and sells bottled pomegranate juice and various pomegranate juice blends, including a pomegranate-blueberry juice blend. *Id.* Pom has been a driving force in the development of the pomegranate and pomegranate juice market. *Id.* 23a-25a. Its efforts have propelled Pom to commercial success. *Id.* 24a.

Coca-Cola is one of Pom's primary competitors in the juice market. JA 25a, 27a-28a. Coca-Cola markets and sells various bottled juices and juice blends under its Minute Maid brand. Pet. App. 1a; JA 25a. In September 2007, Coca-Cola announced the launch of a new "Pomegranate Blueberry" juice product. *Id.* Unbeknownst to consumers, over 99% of Coca-Cola's "Pomegranate Blueberry" juice is actually apple and grape juice. Pet. App. 2a; *see also* JA 23a, 26a. It contains only trivial amounts of pomegranate juice (0.3%) and blueberry juice (0.2%). Pet. App. 2a, 30a. Notwithstanding the actual contents of the product, the front label of Coca-Cola's product is as follows:


Minute
Maid.
POMEGRANATE
BLUEBERRY

CA ER 112 (bottle); *see also* JA 38a (enlarged label).

The overall appearance of the product is unquestionably designed to emphasize pomegranate and blueberry juice. The name "Pomegranate Blueberry" appears in large font—with the words "Flavored Blend of 5 Juices" appearing only in smaller font on a different line below the name. The vignette on the bottle displays a pomegranate and blueberries at least as prominently as an apple and grapes. And Coca-Cola adds coloring so that the contents resemble pomegranate and blueberry juice. *See, e.g.*, JA 39a ("FRUIT AND VEGETABLE JUICES (FOR COLOR)"). Nowhere on Coca-Cola's label are the actual juice percentages disclosed. In fact, Coca-Cola's front label does not even mention the product's overwhelmingly dominant ingredients—apple juice or grape juice—by name.

The summary judgment record in this case confirms that Coca-Cola's "Pomegranate Blueberry" product is, in fact, misleading to consumers. A consumer survey conducted by E. Deborah Jay, President and CEO of the respected Field Research Corporation, revealed unsurprisingly that

> a substantial proportion of potential purchasers of pomegranate and blueberry juice blends are likely to mistakenly believe that [Coca-Cola's juice] mainly contains pomegranate and blueberry juice (and not other types of fruit juice) due to the packaging (the words "pomegranate blueberry" on the front of the bottle and in the product name on the back of the bottle).

JA 96a; *see also* Pet. App. 32a-33a. Indeed, 36% of the consumers who were shown the juice's bottle believed that the juice contains mainly pomegranate and blueberry juice. *See* JA 95a; Pet. App. 32a-33a n.8.

Coca-Cola "has received a record number of complaints" regarding its "Pomegranate Blueberry" product. Pet. App. 31a. A fourteen-year employee of Coca-Cola who has "field[ed] consumer complaints about many products" admitted in deposition testimony (which she later tried to recant) "that there have been no Minute Maid products about which consumers have complained more." *Id.* (internal quotation marks omitted). One consumer, for example, complained:

> Today I made the mistake of buying [the] Minute Maid product that you call "Pomegranate Blueberry[.]" What a crock. It's nothing but fancy apple grape juice. You people are scumbags for mislabeling your products. I'll never buy this product again. I'll never buy Minute Maid products again. And I'll tell all of my friends about this fraud. Thanks for wasting my time and money ....

Id. 31a-32a (alterations and omission in original) (footnote omitted).

None of this came as a surprise to Coca-Cola. To the contrary, prior to the launch of the product, Coca-Cola's Director of Scientific and Regulatory Affairs sent an internal email stating:

> As discussed here is a copy of the front label for the new MM Enhanced Juice Pomegrante [sic] Blueberry product. The product has a blend of apple, grape, pomegranate, blueberry & raspberry juices from conc. We are in compliance with the FDA regs related to the naming of juice containing products. *There is a risk from a misleading standpoint as the product has less than 0.5% of pomegranate and blueberry juices.* [The President and General Manager of

> Minute Maid] is *aware of this issue & is willing to assume the risk.*

Pet. App. 34a-35a (emphases added).

C. Proceedings Below

1. In September 2008 Pom brought this lawsuit under the Lanham Act and California law. Pet. App. 3a. Pom alleged that it had lost sales because Coca-Cola's labeling, marketing, and advertising misled consumers to believe that Coca-Cola's "Pomegranate Blueberry" product consists primarily of pomegranate and blueberry juices, when in fact it consists almost entirely of the less expensive and less desirable apple and grape juices. *Id.*

Coca-Cola moved to dismiss Pom's Lanham Act claim on the ground that Coca-Cola's label complied with FDA juice-naming regulations permitting a beverage to be named after a non-predominant juice in certain circumstances. The district court granted Coca-Cola's motion in part. Pet. App. 83a. The court concluded that Pom's Lanham Act claim was barred by FDA juice-naming regulations to the extent it challenged the name and label of Coca-Cola's "Pomegranate Blueberry" product. *Id.* 89a-91a. The court permitted Pom to pursue its challenge to Coca-Cola's advertising and other marketing of the product. *Id.* 91a-92a. Pom subsequently filed an amended complaint, and, after the district court denied Coca-Cola's motion to dismiss that complaint, the parties conducted discovery. *Id.* 37a, 75a-81a.

The parties then cross-moved for summary judgment. Pet. App. 37a-38a. The district court granted partial summary judgment to Coca-Cola, reiterating its prior ruling that Pom's Lanham Act claim was barred

by FDA's regulations to the extent it challenged Coca-Cola's label. *See id.* 60a-69a.[3]

2. The Ninth Circuit affirmed, holding that "the FDCA and its regulations bar pursuit of both the name and labeling aspects of Pom's Lanham Act claim." Pet. App. 9a. The court of appeals recognized that FDA had never approved the label, *see* Pet. App. 11a-12a, and the court avoided making any definitive pronouncement about whether the label is in fact "authorized" by FDA's regulations. The court explained that it was "primarily guided" in its decision "not by Coca-Cola's apparent compliance with FDA regulations but by Congress' decision to entrust matters of juice beverage labeling to the FDA and by the FDA's comprehensive regulation of that labeling." *Id.* 12a.

The Ninth Circuit acknowledged that FDA apparently had not made any judgment that Coca-Cola's label comports with the FDCA, *see* 21 U.S.C. § 343(a), noting that "FDA has apparently not taken a view on whether Coca-Cola's labeling misleads consumers." Pet. App. 11a-12a. That was true in particular of Coca-Cola's use of a significantly smaller font size for the words "Flavored Blend of 5 Juices" than for the words "Pomegranate Blueberry." The Ninth Circuit found it sufficient that "*so far as we can tell*," the agency had not "*required* that all words in a juice blend's name appear on the label in the same size ...." *Id.* 10a (empha-

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[3] The parties subsequently agreed to entry of judgment with respect to Pom's challenges to Coca-Cola's advertising and other marketing, with Pom preserving its right to appeal the court's motion to dismiss and summary judgment orders. *See* Pet. App. 17a-19a.

ses added). On that view, the court found it sufficient that, "[i]f the FDA believes that [the relative font sizes used in the label] mislead[] consumers, it can act." *Id.* 11a; *see also id.* ("If the FDA believes that more should be done to prevent deception, or that Coca-Cola's label misleads consumers, it can act.").

The Ninth Circuit was similarly noncommittal in its discussion of the name of Coca-Cola's "Pomegranate Blueberry" product, again noting merely that "*as best we can tell*, FDA regulations authorize the name Coca-Cola has chosen." Pet. App. 9a (emphasis added). Indeed, while the Ninth Circuit explained that under FDA's regulations a product's name may reference non-predominant juices if they provide the product's flavor, *see id.*, nowhere did the court point to any evidence that the trace amounts of pomegranate juice and blueberry juice (.3% and .2%, respectively) in fact provide the product's flavor.

Having deemed it irrelevant as a matter of law whether Coca-Cola's label in fact complied with FDA's regulations, the Ninth Circuit expressly left any assessment of that kind to the agency: "[W]e must keep in mind that we lack the FDA's expertise .... In the circumstances here, the appropriate forum for [Pom's] complaints is the [FDA]." Pet. App. 12a (internal quotation marks omitted; second and third alterations in original). The court of appeals thus precluded application of the Lanham Act to a broad range of potentially misleading statements in a variety of diverse contexts solely on the ground that they are subject to "comprehensive" FDA regulation. *Id.*; *see also id.* 8a ("[T]he Lanham Act may not be used as a vehicle to usurp, preempt, or undermine FDA authority."); *id.* 11a ("[F]or a court to act when the FDA has not—despite

regulating extensively in this area—would risk undercutting the FDA's expert judgments and authority.").

SUMMARY OF ARGUMENT

Neither the FDCA nor the Lanham Act contains any provision limiting application of the Lanham Act in challenges to misleading food labels. Because there is no textual basis for an FDA-compliance exception to the Lanham Act, such an exception may be adopted, if at all, only by implication. The presumption against such implied repeals is exceptionally strong: When two federal statutes overlap, both federal statutes must be given effect unless they are in "irreconcilable conflict."

Coca-Cola does not begin to satisfy that demanding standard. Coca-Cola could easily have complied with the FDCA, FDA's juice-naming regulations, and the Lanham Act. Nothing in the FDCA or FDA's regulations required Coca-Cola to design its product in the misleading way it chose. Nor is there any conflict between the purposes and remedies of the two statutes. The Lanham Act protects competitors and can be enforced in private actions by businesses harmed by their competitors' false labeling, including misleading food labels. The FDCA protects public health and safety. It can be enforced only by the government and imposes criminal penalties that must necessarily be construed narrowly. The statutes thus work in tandem to ensure that products are marketed in ways that are both safe for consumers and not unfair to competitors.

Indeed, the structure and history of the FDCA strongly indicate that Congress intended *not* to preclude Lanham Act claims in the realm of food labeling. The Lanham Act has been used to challenge food labeling for decades. Yet Congress has not enacted any

provision purporting to preclude those kinds of claims. The absence of any express preclusion is particularly conspicuous because in 1990 Congress *did* add an express state-law preemption provision to the FDCA's regulation of food labeling. Had Congress intended to foreclose Lanham Act suits challenging food labels, it easily could have done so as part of that enactment.

The conclusion that the FDCA does not preclude application of the Lanham Act to misleading juice labels follows inexorably from this Court's holding in *Wyeth* v. *Levine*, 555 U.S. 555 (2009), that FDA's approval of a drug label does not displace state failure-to-warn suits challenging the adequacy of the warning. *Wyeth* involved FDA's implementation of the FDCA in a manner that reflected the agency's substantive judgment about the label's adequacy. FDA specifically approved, and mandated use of, the precise wording on Wyeth's label; at that time, it was uncertain whether Wyeth was even permitted to alter the label without prior permission; and FDA contended that state tort law was preempted. This Court nonetheless concluded that the state-law challenge was not preempted, holding that the FDCA merely sets a floor upon which other laws can build. Following *Wyeth*, there can be no serious argument that the provisions of the FDCA at issue in this case are in "irreconcilable conflict" with the Lanham Act. FDA does not even generally *review*—much less approve—particular food labels; nothing even arguably prevented Coca-Cola from designing its label to avoid misleading consumers; and FDA has given no indication that its juice-naming rules set the outer bounds of labeling regulation. Moreover, as with respect to the claim at issue in *Wyeth*, Congress has declined to enact a provision precluding Lanham Act chal-

lenges to food labels despite decades of coexistence between the Lanham Act and the FDCA.

The Ninth Circuit's contrary holding did not apply this Court's "irreconcilable conflict" precedents or even acknowledge *Wyeth*. Instead, the court found that FDA's mere regulatory authority under the FDCA displaced the Lanham Act. To reach this conclusion, the court misapplied principles drawn from the doctrines of field preemption and primary jurisdiction—neither of which applies here.

Tellingly, Coca-Cola has not even attempted to defend the court of appeals' rationale. It has argued instead that Pom's claim is foreclosed because FDA's regulations allegedly "specifically authorize" Coca-Cola's label. This is beside the point because even if Coca-Cola's label is in compliance with those regulations, there is no irreconcilable conflict between the Lanham Act and the regulations. In any event, FDA's juice-naming regulations do not "specifically authorize" Coca-Cola's misleading product. It is undisputed that FDA has not reviewed and approved Coca-Cola's label. And FDA has stated unequivocally that the mere fact that the name of a juice comports with FDA's naming regulation does not mean that the label as a whole is not misleading. Here, Pom alleges that Coca-Cola's product and its label—taken as a whole—mislead consumers and damage Pom. Several features of the label are not addressed by FDA regulations. For example, as the Ninth Circuit itself recognized, no FDA regulation authorizes Coca-Cola to use markedly larger type for the words "Pomegranate" and "Blueberry" than the FDA-required phrase "Flavored Blend of 5 Juices." The regulations also do not approve the outsized image of the pomegranate and blueberry fruits or the use of coloration to reinforce these misleading elements. All

these features taken together mislead consumers and injure Pom, and none is addressed by FDA's juice-naming regulations. Finally, it is not at all clear that the name Coca-Cola has chosen in fact comports with FDA's regulations. Indeed, Coca-Cola's arguments in this Court strongly suggest it does not.

Congress could not have intended the far-reaching negative consequences of the Ninth Circuit's untethered and expansive holding. The Ninth Circuit's approach would leave regulation of misrepresentations made in connection with product labeling almost entirely in the hands of FDA. But it has long been understood that FDA does not have anywhere near the resources necessary to police food labeling. Precluding Lanham Act challenges to misleading food labels would thus create a significant enforcement gap that Congress could not have desired. Under the Ninth Circuit's approach, moreover, any time an agency has broad authority to regulate labeling or potentially misleading commercial practices, that regulation could preclude private actions under the Lanham Act. But Congress has recognized the importance of the Lanham Act's prohibition on false advertising in deterring unfair competition, and there is no reason to think Congress intended to repeal that prohibition *sub silentio*.

ARGUMENT

I. THE FOOD, DRUG, AND COSMETIC ACT DOES NOT PRECLUDE FALSE ADVERTISING CLAIMS BROUGHT UNDER THE LANHAM ACT

A. Lanham Act Challenges To Misleading Food Labels Are Not Expressly Precluded

The interpretation of a statute, of course, "begin[s] with the text." *Arlington Cent. Sch. Dist. Bd. of Educ.* v. *Murphy*, 548 U.S. 291, 296 (2006). "When the statutory 'language is plain, the sole function of the courts—at least where the disposition required by the text is not absurd—is to enforce it according to its terms.'" *Id.* at 296-297 (quoting *Hartford Underwriters Ins. Co.* v. *Union Planters Bank, N.A.*, 530 U.S. 1, 6 (2000)). Nothing in the Lanham Act or the FDCA provides any textual support for the conclusion that Pom's Lanham Act claim is precluded by the FDCA. The governing provision of the Lanham Act is unequivocal:

> Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce *any* word, term, name, symbol, or device, or any combination thereof, or any ... false or misleading description of fact, or false or misleading representation of fact, which ... in commercial advertising or promotion, *misrepresents the nature, characteristics, qualities, or geographic origin* of his or her or another person's goods, services, or commercial activities, shall be liable[.]

15 U.S.C. § 1125(a)(1), (B) (emphases added). Thus, by its plain terms, the Lanham Act mandates that Coca-Cola not misrepresent the nature or characteristics of its product. Nothing in the Lanham Act provides support for the FDA-compliance exception urged by Coca-

Cola—much less for the Ninth Circuit's sweeping exception based on FDA's mere regulatory authority or purportedly "comprehensive regulation." Pet App. 12a.

Nor can any textual support for preclusion be found in the FDCA. The FDCA provides that food is "deemed to be misbranded" in a variety of circumstances. 21 U.S.C. § 343. But it nowhere purports to displace the Lanham Act. The same goes for FDA's implementing regulations, which Coca-Cola invokes in its defense. Those regulations address various aspects of food labeling, including labeling of juice products. *See, e.g.*, 21 C.F.R. § 102.33(b)-(d). But nowhere do they contain any provision purporting to bar Lanham Act claims. *See Cottrell, Ltd.* v. *Biotrol Int'l, Inc.*, 191 F.3d 1248, 1256 (10th Cir. 1999) (refusing to dismiss Lanham Act claim that "touches on issues covered by" the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) because "nowhere" does FIFRA "explicitly preclude Lanham Act coverage").

B. There Is No Conflict—Much Less The Required Irreconcilable Conflict—Between The Lanham Act And The FDCA

This Court has repeatedly instructed that "absent 'a clearly expressed congressional intention,'" courts must give full effect to allegedly competing federal statutes unless they are "in 'irreconcilable conflict,' or where the latter Act covers the whole subject of the earlier one and 'is clearly intended as a substitute.'" *Carcieri* v. *Salazar*, 555 U.S. 379, 395 (2009); *see also Branch* v. *Smith*, 538 U.S. 254, 273 (2003) (plurality opinion) (quoting *Morton* v. *Mancari*, 417 U.S. 535, 551 (1974), and *Posadas* v. *National City Bank*, 296 U.S. 497, 503 (1936)).

Thus, when considering two federal statutes that contain no express preclusion but are nonetheless claimed to be in conflict, "it is the duty of the courts ... to regard each as effective" if they "are capable of coexistence." *Morton*, 417 U.S. at 551. This Court will "not infer a statutory repeal 'unless the later statute "expressly contradict[s] the original act"' or unless such a construction 'is absolutely necessary ... in order that [the] words [of the later statute] shall have any meaning at all.'" *National Ass'n of Home Builders* v. *Defenders of Wildlife*, 551 U.S. 644, 662-663 (2007) (quoting *Traynor* v. *Turnage*, 485 U.S. 535, 548 (1988) (alterations in original)). Even statutes that "overlap" or may appear to be somewhat "redundan[t]" can be "fully capable of coexisting" and should be given full effect so long as no irreconcilable conflict exists. *United States* v. *Batchelder*, 442 U.S. 114, 118 (1979) (overlapping criminal statutes imposing different maximum terms of imprisonment for nearly identical conduct held "fully capable of coexisting").

This high bar for implied preclusion is rooted in separation of powers principles. As the Court has explained, the rule against implied repeals is dictated by two "superior values": In addition to "harmonizing different statutes," this rule "constrain[s] judicial discretion in the interpretation of the laws." *Astoria Fed. Sav. Loan Ass'n* v. *Solimino*, 501 U.S. 104, 109 (1991). Without a strong presumption that potentially competing federal laws should be given full effect whenever possible, courts would be "at liberty to pick and choose among congressional enactments" whenever two federal statutes happen to overlap. *Morton*, 417 U.S. at 551. This Court has categorically rejected that approach. *Id.*

1. Coca-Cola can easily comply with both the Lanham Act and the FDCA and FDA's regulations

The Lanham Act and the FDCA's regulation of food labeling "are fully capable of coexisting," *Batchelder*, 442 U.S. at 122, because Coca-Cola "can easily satisfy both mandates," *Department of Transp.* v. *Public Citizen*, 541 U.S. 752, 767 (2004): It can refrain from harming competitors through its deceptive product label (as required by the Lanham Act) while at the same time selling a product that is not misbranded (as required by the FDCA). As applied here, the Lanham Act simply prohibits Coca-Cola from making false or misleading descriptions or representations regarding its juice product. 15 U.S.C. § 1125(a)(1). Certainly, neither the FDCA's statutory provisions on food labeling nor FDA's implementing regulations require Coca-Cola to engage in such conduct.

Coca-Cola was not required to use the misleading name it selected for its product. The FDCA's provision relating to food-naming, 21 U.S.C. § 343(i), states in relevant part that, for a food not to be misbranded, the label must "bear[] (1) the common or usual name of the food, if any there be"; and, (2) if the food is "fabricated from two or more ingredients, the common or usual name of each such ingredient." *Id.* Nothing in § 343(i) required Coca-Cola to omit the beverage's two predominant juices and name the product "Pomegranate Blueberry"—even though the product contains 99.4% apple juice and grape juice and .5% pomegranate and blueberry juice combined. Pet. App. 2a.

Likewise, Coca-Cola does not—and cannot—argue that anything in FDA's juice-naming regulation, 21 C.F.R. § 102.33, required it to give its product the mis-

leading name it chose. Section 102.33 specifies ways in which a juice product's label *can* satisfy the statutory requirement set forth in 21 U.S.C. § 343(i). In some circumstances, the regulation permits a product containing multiple juices to be labeled using the name of a non-predominant juice if the label indicates that the product is a "blend" of juices and is "flavored" with the non-predominant juice. *See* 21 C.F.R. § 102.33(c), (d)(1). But this is merely an option. The regulations do not mandate that the name of a juice blend omit reference to the juices comprising more than 99% of the beverage—as Coca-Cola chose to do here. *See id.* § 102.33(c) ("*If* a ... blend of single-strength juices contains ... a juice other than the named or implied juice .... (emphasis added)), (d) ("*where* one or more, but not all, of the juices are named on the label ... and *where* the named juice is not the predominant juice ..." (emphases added)). Nor do they mandate that Coca-Cola's label omit reference to the minimal percentage contribution of pomegranate and blueberry juices. In fact, § 102.33(d)(2) specifically provides that, if a party elects to name its product after a non-predominant juice, it *can* choose to indicate on the label the percentage of the drink comprised by that juice, so as not to mislead consumers. Coca-Cola chose not to do so.

Similarly, nothing in the FDCA or FDA's regulations required Coca-Cola to craft an overall product label that is grossly misleading. It was not required to shrink the font size of the words "Flavored Blend of 5 Juices" relative to the size of the product name "Pomegranate Blueberry." It was not required to include a vignette on the bottle that displays a pomegranate and blueberries at least as prominently as an apple and grapes. And it was not required to color the beverage a deep purple so that it resembles blueberry-

pomegranate juice. Coca-Cola did not do any of these things to comply with an FDA regulation; it did them because it wanted consumers falsely to believe that the company's "Pomegranate Blueberry" juice was made with appreciable amounts of pomegranate and blueberry juice.

Nothing in the FDCA purports to protect misleading labels from challenge. To the contrary, the FDCA addresses attempts to exploit gaps in the regulation of specific aspects of food labeling by broadly *prohibiting* labeling that is "false or misleading in any particular." 21 U.S.C. § 343(a); *see also id.* § 321(n) (in "determining whether the labeling ... is misleading there shall be taken into account (among other things) not only representations made or suggested ... , but also the extent to which the labeling ... fails to reveal facts material in the light of such representations"). The FDCA also separately *prohibits* obscuring any required label material by strategically shrinking its font size. *See id.* § 343(f) (required label material must be displayed "prominently" on the label "with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use").

In short, nothing in the FDCA or FDA's regulations prevented Coca-Cola from making its label nonmisleading—and thus compliant with the Lanham Act. "Without a conflict," Coca-Cola "must comply with all of its statutory mandates." *Public Citizen*, 541 U.S. at 767; *see also Wyeth*, 555 U.S. at 573 ("Impossibility preemption is a demanding defense" that is not met where defendant "has failed to demonstrate that it was impossible for it to comply with both federal and state re-

quirements."); *Nader* v. *Allegheny Airlines, Inc.*, 426 U.S. 290, 299-300 (1976) (finding no "irreconcilable conflict between the statutory scheme [then in force] and the persistence of common-law remedies" where "[t]here is no [statutory or regulatory] *requirement* that [defendant] engage in" the actionable conduct (emphasis added)).

2. The Lanham Act's and FDCA's purposes and remedies confirm that the two laws can and do coexist

The distinct—but complementary—purposes of the Lanham Act and FDCA confirm that the two statutes easily coexist. *See, e.g., J.E.M. Ag Supply, Inc.* v. *Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 144 (2001) (two overlapping laws with "different requirements and protections" should both be regarded as effective); *Board of Supervisors* v. *Lackawana Iron & Coal Co.*, 93 U.S. 619, 623 (1876) (no irreconcilable conflict where the statutes' "scope and purposes are distinct and different").

The Lanham Act aims to "protect persons engaged in [interstate] commerce against unfair competition." 15 U.S.C. § 1127. It advances this objective by "provid[ing] a private remedy to a commercial plaintiff" whose "commercial interests" have been harmed by another party's false advertising. *Sandoz*, 902 F.2d at 230. Consumers, by contrast, lack prudential standing to bring such actions. *See, e.g., Made in the USA Found.* v. *Phillips Foods, Inc.*, 365 F.3d 278, 279-280 (4th Cir. 2004) (collecting cases); *Conte Bros. Auto., Inc.* v. *Quaker State-Slick 50, Inc.*, 165 F.3d 221, 229 (3d Cir. 1998) (Alito, J.); *Seven-Up Co.* v. *Coca-Cola Co.*, 86 F.3d 1379, 1383 n.5 (5th Cir. 1996); *Colligan* v. *Activities Club of New York, Ltd.*, 442 F.2d 686 (2d Cir. 1971).

Thus, while the Lanham Act's prohibition on false advertising undoubtedly benefits both consumers and commercial entities, the statute is "primarily intended to protect commercial interests." *Sandoz*, 902 F.2d at 230.

The FDCA's misbranding provisions serve a different purpose: They are designed to protect the public's health and safety. *See 62 Cases of Jam* v. *United States*, 340 U.S. 593, 596 (1951) ("The purposes of this legislation ... 'touch phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection.'"); *Holk* v. *Snapple Beverage Corp.*, 575 F.3d 329, 331-332 (3d Cir. 2009) (FDCA motivated by "[m]ounting public concern over unsafe food and drugs" in the 1930s). The responsibility for enforcing noncompliance with the statute, as such, has remained with FDA, not private parties. 21 U.S.C. § 337(a) ("[A]ll ... proceedings for the enforcement, or to restrain violations, of this [Act] shall be by and in the name of the United States.").[4]

The statutes' purposes are therefore distinct, albeit overlapping and complementary. FDA enforcement of the FDCA's public health goals is not undermined by private competitors' efforts to prevent unfair competition under the Lanham Act. To the contrary, the statutes' respective purposes and requirements work in tandem to ensure that products are marketed in ways

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[4] In the NLEA, Congress authorized state authorities to enforce noncompliance with certain misbranding provisions of the FDCA through civil enforcement and injunctive proceedings if certain circumstances are satisfied. Pub. L. No. 101-535, § 4, 104 Stat. 2353, 2362 (1990) (21 U.S.C. § 337(b)).

that are *both* safe for consumers and not unfair to competitors.

There is likewise no basis to believe that the availability of private remedies under the Lanham Act in the food labeling context could interfere with FDA's enforcement of the FDCA itself. As discussed *infra* pp. 29-32, in enacting the NLEA, Congress preempted state laws only to a limited extent, and expressly disclaimed preemption as to all other state-law claims. Under this provision, States are free to impose civil liability for violations of the FDCA's misbranding provisions. It necessarily follows that the availability of nationally uniform private remedies under the Lanham Act poses no conflict with FDA's enforcement of the FDCA.

Even aside from the NLEA's preemption provision, moreover, there is no tension—much less conflict—between the respective remedial schemes of the FDCA and Lanham Act. In the public health context of the FDCA, Congress determined that enforcement of the FDCA's "floor" requirements should include criminal liability and other regulatory penalties. *See* 21 U.S.C. § 343 (defining misbranding), § 331 (prohibiting misbranding), § 333(a) (criminal penalties), § 334(a)(1) (seizure). By contrast, in the commercial context of the Lanham Act, Congress opted to rely on private parties and traditional civil remedies to address the commercial wrong of false advertising. *See, e.g.*, 15 U.S.C. § 1116(a) (injunctive relief), § 1117(a) (profits, damages, and costs); *see also Coca-Cola Co.* v. *Procter & Gamble Co.*, 822 F.2d 28, 31 (6th Cir. 1987) ("[C]ompetitors have the greatest interest in stopping misleading advertising, and a private cause of action under section 43(a) allows those parties with the greatest interest in enforcement ... to enforce the statute rigorously.").

The two statutes' respective remedial schemes thus properly reflect the distinct purposes of each: The Lanham Act's less severe civil remedies preserve integrity in competition, whereas the FDCA's criminal and other public sanctions provide a backdrop deterrent intended to ensure minimum levels of public health, safety, and understanding in the food industry. *See Batchelder*, 442 U.S. at 122 (no conflict where different maximum penalties applied to convictions under different, albeit overlapping, statutes). Indeed, as the Court explained in *Wyeth*, civil remedies through private actions can be a fully "complementary form of ... regulation" that compensates in part for FDA's own "limited resources." 555 U.S. at 578-579; *see also infra* pp. 52-54.

3. Congress has declined to preclude Lanham Act challenges to misleading food labels

Congress has given no indication whatsoever that it believes application of the Lanham Act to misleading food labels conflicts with the FDCA. The FDCA was enacted in 1938. Pub. L. No. 75-717, 52 Stat. 1040 (1938). Eight years later, Congress enacted the Lanham Act's prohibition on false advertising. Pub. L. No. 79-489, § 43, 60 Stat. 427, 441 (1946). In the subsequent sixty years, Congress has repeatedly amended both. These amendments have included both a redrafting of § 1125(a) as part of the Trademark Law Revision Act of 1988, *see* Pub. L. No. 100-667, § 132, 102 Stat. 3935, and enactment of the NLEA in 1990. *See also supra* nn.1, 2. To paraphrase this Court's observation in *Wyeth*, 555 U.S. at 574: "If Congress thought [Lanham Act] suits posed an obstacle to its objectives, it surely would have enacted an express [preclusion] provision at some point during the FDCA's 70-year history."

Indeed, quite to the contrary, Congress has declined to preclude application of the Lanham Act to food-labeling claims despite expressly defining the preemptive reach of the FDCA. When Congress amended the FDCA in the NLEA in 1990, it enacted detailed provisions explicitly governing the preemptive scope of the FDCA's food-labeling requirements. *See* Pub. L. No. 101-535, § 6, 104 Stat. 2353, 2362-2364 (21 U.S.C. § 343-1 & note). In doing so, however, Congress limited the effect of those provisions to *state*-law requirements (and only certain of those). It did not displace Lanham Act challenges to food labels.[5]

Congress was well aware that the Lanham Act applied to misleading food labels when it decided to displace only state-law labeling requirements. The NLEA was enacted against the backdrop of cases challenging food labels under the Lanham Act's prohibition on false advertising. *See, e.g., Hesmer Foods, Inc.* v. *Campbell Soup Co.*, 346 F.2d 356, 359 (7th Cir. 1965) (Lanham Act challenge to product named "Barbecue Beans" despite the fact it neither contains meat nor was cooked over an open fire); *Potato Chip Inst.* v. *General Mills, Inc.*, 333 F. Supp. 173 (D. Neb. 1971) (challenge to package label describing dehydrated potato product "CHIPOS" as potato chips), *aff'd*, 461 F.2d 1088 (8th Cir. 1972) (per curiam). Indeed, testimony at the hearings that ultimately led to enactment of the NLEA made clear that

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[5] Indeed, the legislative history of the NLEA confirms what is apparent on the face of § 343-1: the NLEA's preemption provision was a "carefully crafted" provision that was "limited in scope" and represented the result of congressional "compromise." 136 Cong. Rec. 33,425, 33,429 (1990) (Sen. Hatch); *see also* 136 Cong. Rec. 20,414, 20,418 (1990) (Rep. Waxman).

the Lanham Act was available—and in fact being used—to challenge food claims:

> There is also the Lanham Act, which says that if you ... create a false impression about your product versus some other product, you can be sued by other companies that say that this is injuring them. There have been a number of food Lanham Act suits where millions of dollars of penalties have been brought forward.

Health and Nutrition Claims in Food Advertising and Labeling, Hearing Before the S. Comm. on Gov't Affairs, 101st Cong. 74 (1990) (statement of Daniel L. Jaffe, Executive Vice President, Ass'n of Nat'l Advertisers) ("1990 Senate Hearings"); *see also FDA's Continuing Failure to Regulate Health Claims for Foods, Hearings Before the Subcomm. on Human Res. and Intergov'tl Relations of the H. Comm. on Gov't Operations*, 101st Cong. 157, 431 (1989) (testimony by OIRA officials regarding OMB memorandum stating, in connection with regulation of health claims on food products, that "manufacturers have strong incentives to avoid costly product liability and Lanham Act exposure"). Congress was thus well aware of the use of the Lanham Act to combat deceptive food labeling. *See United States* v. *Rutherford*, 442 U.S. 544, 554 & n.10 (1979) ("That Congress is aware of the [agency's] policy ... is evident from Senate Subcommittee hearings").

Congress' decision to preempt only certain types of state labeling requirements further confirms that Congress did not intend to displace laws, like the Lanham Act, that generally prohibit misleading labeling. In the NLEA, Congress enacted a saving clause that makes clear that the NLEA does not preempt state laws falling outside of the law's express preemption provision:

"The [NLEA] shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under [21 U.S.C. § 343-1]." NLEA § 6(c)(1) (21 U.S.C. § 343-1 note). And the NLEA's express preemption provision, by its terms, displaces only a specified class of state laws: those state laws that purport to impose food labeling requirements "of the type" imposed by *certain* enumerated provisions of the FDCA that are not "identical" to the requirements in those provisions. *See* 21 U.S.C. § 343-1(a)(2), (3). Critically, in enumerating the FDCA provisions that trigger this (qualified) preemption, Congress *omitted* the FDCA's prohibition of labeling that is "false or misleading in any particular," *id.* § 343(a).

Congress' exclusion of § 343(a) from the list of provisions set forth in § 343-1 makes plain its determination that even the application of *state* laws imposing requirements "of the type" of § 343(a)—*i.e.*, provisions that generally prohibit the "false or misleading" labeling of food—would be consistent with the FDCA's food-labeling framework. The NLEA's limited preemption provision was motivated by the need for "[n]ational uniform[ity]" across the 50 states in certain technical aspects of food labeling. 21 U.S.C. § 343-1 (section title); *see also* 136 Cong. Rec. at 20,418 (Rep. Waxman) ("A national food processor understandably finds it difficult to comply with numerous conflicting and inconsistent State and local laws."). Laws that generally prohibit false or misleading labeling, however, do not impose inconsistent technical labeling mandates across jurisdictions; they make actionable misleading conduct that has no redeeming value by applying a "'single, uniform'" standard. *Altria Group, Inc.* v. *Good*, 555 U.S. 70, 79-80 (2008); *see also id.* at 82.

This statutory scheme renders implausible any contention that, after specifically *preserving* from preemption by the NLEA state-law claims "of the type" generally prohibiting false or misleading labeling, 21 U.S.C. §§ 343(a), 343-1(a) & note, Congress could have intended to displace the Lanham Act—a uniformly applicable *federal* counterpart to those un-preempted state laws.

4. As in *Wyeth*, the FDCA and FDA's regulations set only a "floor" upon which other laws can build

Nothing in the FDCA, the NLEA, FDA's regulations, or the preambles to those regulations suggests that, through its regulations, FDA was tasked or even intended to define the outer contours of what makes a juice label misleading. Rather, even more so than in *Wyeth*, FDA's regulations bespeak an intent to set a floor—but not a ceiling—on the adequacy of labeling.

Wyeth involved a state tort failure-to-warn claim against a drug manufacturer alleging that certain safety information should have been included on the warning label but was not. *See* 555 U.S. at 558. The Court acknowledged that "FDA's premarket approval of a new drug application includes the approval of the exact text in the proposed label." *Id.* at 568. Although the Court determined that under a particular regulation, Wyeth could have provisionally altered the approved label to strengthen the warning at issue, that issue was contested by FDA itself. *See id.* at 569-572; Brief for the United States as Amicus Curiae Supporting Petitioner ("U.S. Br."), *Wyeth* v. *Levine*, 555 U.S. 555, 2008 WL 2308908, at *21-25 (June 2, 2008). The Court held that despite FDA's specific approval of the precise label being challenged, the plaintiff's tort claim was not preempted. *Wyeth*, 555 U.S. at 581. In reaching this

holding, the Court rejected Wyeth's argument that "requiring it to comply with [state law] ... would obstruct the purposes and objectives of federal drug labeling regulations." *Id.* at 573.

The Court's analysis in *Wyeth* confirms that there is no conflict between the FDCA and the Lanham Act in this case. Although *Wyeth* involved preemption, not preclusion of another federal statute, the teachings of *Wyeth* apply here. In *Wyeth*, the Court asked whether state law "creates an unacceptable 'obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" 555 U.S. at 563-564 (quoting *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941)). The standard in this preclusion case is the more demanding "irreconcilable conflict" standard. *See, e.g.*, *Morton*, 417 U.S. at 550-551. For the same reasons the lower standard for obstacle preemption could not be met in *Wyeth*, so too here there is no irreconcilable conflict between the Lanham Act and the FDCA.

a. In *Wyeth*, the Court first reviewed the history of federal regulation of drugs and drug labeling in order to discern "Congress' purposes" with respect to preemption in enacting the FDCA. 555 U.S. at 574. Relying heavily on Congress' "silence," *id.* at 575, on the issue despite the availability of state tort law "during the FDCA's 70-year history," *id.* at 574, the Court concluded that "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness," *id.* at 575. In this case, the evidence on this score is at least as powerful. As noted, the Lanham Act and the FDCA have coexisted for over sixty years, and at no point during this history did Congress preclude Lanham Act claims, despite multiple amendments of both statutes and enactment of a detailed provision preempting state law. *See supra* pp. 28-30.

b. Unlike with respect to the prescription drug at issue in *Wyeth*, FDA does *not* approve or disapprove food and beverage labels. *See* Pet. App. 12a ("The FDA has not established a general mechanism to review juice beverage labels before they reach consumers."). Further, as the Solicitor General has confirmed, there is no basis for Coca-Cola to construe the absence of pending FDA proceedings as tacit FDA approval of its product label. *See* Brief of the United States As Amicus Curiae ("U.S. Pet. Br.") 16; *Heckler* v. *Chaney*, 470 U.S. 821, 831 (1985) (listing "many" reasons why an agency may decide not to pursue enforcement action); *Altria Group*, 555 U.S. at 89-90. To the contrary, inferring approval from lack of enforcement would be particularly unwarranted, as FDA's enforcement for misbranding of food and beverages is nearly nonexistent. *See infra* pp. 52-54.

Thus, the case for preclusion here is far weaker than the (unsuccessful) case for preemption in *Wyeth*. There, the Court refused to find "obstacle" preemption—a standard that is itself *less* stringent for defendants than the one applicable here—even where the applicable FDCA provisions and FDA regulations *did* require affirmative FDA approval of Wyeth's prescription drug label and Wyeth had repeatedly secured the required approval. *See* 555 U.S. at 561-563. That even mandatory, affirmative FDA approval was held in *Wyeth* to set only a regulatory "floor" is fatal to Coca-Cola's claims.

c. The Court in *Wyeth* found no preemption even though FDA had taken the position that "'FDA approval of labeling ... preempt[ed] conflicting or contrary State law.'" 555 U.S. at 575. Here, FDA has made clear that compliance with one aspect of its juice-

naming regulations does not, by itself, render a juice label non-misleading.

In the preamble to its 1993 rulemaking, FDA explained that the general juice-naming scheme it was adopting—*e.g.*, allowing multiple-juice blends in some circumstances to be named after non-predominant juices if they provide the characterizing flavor and the name included the phrases "blend of juices"—"would provide adequately descriptive labeling *for some products*." 58 Fed. Reg. 2897, 2920 (Jan. 6, 1993) (emphasis added). But it stressed that the agency "does not agree that this scheme would ensure that *all* multiple-juice beverages would bear labels that are not misleading." *Id.* (emphasis added); *see also id.* ("FDA agrees with those comments that expressed concern that consumers are being misled into believing that named juices are present in greater amounts than is actually the case. The agency is aware of a number of products currently on the market for which the suggested labeling would not inform the consumer that the named juice is present in only a minor amount."). Similarly, although 21 C.F.R. § 102.33(b) permits a non-predominant juice to appear first in a product name if that juice provides a characterizing flavor, FDA has cautioned that "there is great potential for [such a] label to misrepresent the contribution of the named juice to the product" and that "this provision *does not relieve the manufacturer* of the obligation to label the product in a truthful and nonmisleading manner." 58 Fed. Reg. at 2920 (emphasis added).

FDA stressed that, in some circumstances, "the disclosure of the amount of a characterizing ingredient is a material fact." 58 Fed. Reg. at 2921. FDA explained:

> The agency notes that the regulation on the general principles for common and usual names provides in § 102.5(b) (21 CFR 102.5(b)) that when the proportion of a characterizing ingredient in a food has a material bearing on price or consumer acceptance, or when the label or labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient is present in an amount greater than is actually the case, the percentage [of] such characterizing ingredient shall be declared as a part of the common or usual name of the food.

Id. at 2920. Likewise, FDA noted that the use of vignettes on an otherwise-appropriate label can also raise misbranding concerns. *See id.* at 2922 ("[FDA] will determine on a case-by-case basis whether a vignette is misleading because it is not consistent with other label information *or for other reasons*." (emphasis added)); *id.* ("[F]or a beverage label to not be misleading, it is necessary that the vignette and other label statements on the beverage not conflict in any way."). Indeed, in this case, FDA confirms that it has *not* "marked the metes and bounds of all possible misleading material on juice labels." U.S. Pet. Br. 11-12.

FDA also made clear in the 1993 preamble that its regulations are not intended to prevent juice manufacturers from providing more information than they require. Although FDA's regulation permits a juice product in some circumstances to omit from its name some of the juices it contains, FDA stated that it affirmatively "encourage[s]" that "each juice in a beverage be declared in the name of the product." 58 Fed. Reg. at 2919.

FDA's enforcement positions confirm that FDA regulations merely set a floor on the requisites of food labeling. In 2009, for example, FDA issued a warning letter to a juice manufacturer asserting that two of its juice blend products were "misbranded under section 403(a)(1) of the Act [21 USC 343(a)(1)] because their labels [we]re misleading."[6] Each label used a non-predominant juice in the product name and included the caveat that the product was "flavored" and a "blend." Nonetheless, FDA invoked 21 U.S.C. § 343(a)(1)—which generally prohibits "labeling ... [that] is false or misleading in any particular"—and found the labels misleading because they were "designed to imply that the product[s] [were] 100% [non-predominant] juice."

In support of its conclusion, FDA relied on several aspects of the label without ever pointing to a specific FDA regulation. The agency first pointed to the labels' emphasis on the non-predominant juices: "The principal display panels identify the products as 'Orange Tangerine' and 'Grape,' respectively, in large, bold lettering outlined in black; however, neither orange/tangerine juice nor grape juice is the predominant juice in the products." Then, FDA identified additional factors supporting its conclusion—the "close proximity" of the words "All Natural 100% Juice" to the named juices and the fact that the "flavored" and "blend" caveats were at the bottom of the labels in small, white font. FDA's targeting of juice labels that seemingly comply with FDA's discrete juice-naming regulations confirms

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[6] *See* Warning Letter from Roberta F. Wagner, FDA, to Brad Alford, Nestle U.S.A., Dec. 4, 2009, *available at* http://www.fda.gov/iceci/enforcementactions/warningletters/ucm194122.htm.

that FDA has not viewed its regulations as setting a limit on the ways in which juice labels can be misleading.

d. Adjudication of Pom's Lanham Act claim poses no risk of frustrating the policy objectives reflected in FDA's regulations. As just explained, FDA has disclaimed that compliance with 21 C.F.R. § 102.33 will assure that a product's label or even its name will be non-misleading. Thus, a finding in this action that Coca-Cola's product name is in fact misleading would not be in tension with FDA's position reflected in the 1993 preamble and 2009 Warning Letter referenced above. Moreover, as the Solicitor General recognizes, Pom's challenge to the non-naming aspects of Coca-Cola's label is not even arguably in tension with FDA's policy judgments because FDA has not issued regulations relating to those aspects of Coca-Cola's label. *See* U.S. Pet. Br. 18-19; Pet. App. 10a-11a; *see also infra* pp. 47-49.

In any event, even if FDA had determined that *all* labels complying with § 102.33(d)(1) are necessarily non-misleading, permitting Pom's claim to go forward still would not thwart FDA's policy objectives. This is not a situation in which an agency has sought to encourage the conduct being challenged in order to advance the ultimate purpose of the regulation. For example, in *Geier* v. *American Honda Motor Co.*, 529 U.S. 861 (2000), the Court found preempted a state-law duty to install airbags in all new vehicles where the Department of Transportation had rejected the "'all airbag'" standard in favor of a "gradual phase-in of a mix of passive restraints" instead. *Wyeth*, 555 U.S. at 580 (citing *Geier*, 529 U.S. at 879). The Court reasoned that, in opting for a phased-in approach, the agency had balanced the safety advantages of an immediate "'all air-

bag'" standard against a phase-in strategy that "would ... lower costs, overcome technical safety problems, encourage technological development, and win widespread consumer acceptance—all of which ... promoted[d] [the regulation']s safety objectives." *Geier*, 529 U.S. at 875; *id.* at 881 (adopting view that regulation "'embodie[d] the Secretary's policy judgment that safety would best be promoted if manufacturers installed *alternative* protection systems in their fleets rather than one particular system in every car.'"). Imposing an all-airbag standard under state law would have upset that balance. *Id.*

Nothing remotely equivalent is at issue in this case. FDA does not have a policy of encouraging manufacturers to name their blended juices after ingredients that are present only in trace amounts. To the contrary, consistent with the FDCA's goal of fostering public health through consumer understanding, FDA has "*encourage[d]*" that "each juice in a beverage be declared in the name of the product." 58 Fed. Reg. at 2919 (emphasis added). Thus, at most, FDA provided § 102.33(d)(1) as an option while still encouraging manufacturers to provide more information to consumers in their juice products' names. There is no basis to conclude in these circumstances that FDA believed that allowing labels like Coca-Cola's was necessary to pursue "a significant regulatory objective." *See Williamson* v. *Mazda Motor of Am., Inc.*, 131 S. Ct. 1131, 1137 (2011).

Indeed, the coexistence of Lanham Act claims and the FDCA in the context of misleading food labels poses a much easier question than even the one confronted in *Wyeth*. There, the continued availability of failure-to-warn claims under state law raised a risk of "over-warning" and thus a plausible need by the agency to

balance potentially countervailing policy interests. *See, e.g.*, U.S. Br., *Wyeth* v. *Levine*, *supra*, 2008 WL 2308908, at *17 ("[L]abeling must strike a balance between notifying users of potential dangers and not unnecessarily deterring beneficial uses through overwarning."); *see also id.* at *8, *16-17. Here, there is no such offsetting concern. If the legitimate countervailing interest in *Wyeth* did not turn FDA's judgments into a regulatory "ceiling," it is impossible to conclude that FDA's food labeling regulations do so here. In the same way that state laws offer "an additional, and important, layer of consumer protection that complements FDA regulation," *Wyeth*, 555 U.S. at 579, the Lanham Act provides a layer of competitor and consumer protection that the FDCA does not address. This case follows *a fortiori* from *Wyeth*.

C. There Is No Support For The Ninth Circuit's Sweeping Theory Of Field Preclusion

The Ninth Circuit did not conduct an "irreconcilable conflict" analysis or consider any of the many indications discussed above that the two statutes do not irreconcilably conflict. The court did not identify a single provision of the FDCA that is even arguably in tension with the Lanham Act. Nor did the court acknowledge this Court's holding in *Wyeth* that the FDCA merely sets a "floor" for regulation of labels on which other laws can build. 555 U.S. at 577-578. Rather, the court rested principally on its perception that Congress had "entrust[ed] matters of juice beverage labeling to the FDA" and on what it misperceived as "FDA's comprehensive regulation of that labeling." Pet. App. 12a. The Ninth Circuit thus appeared to apply concepts more akin to field preemption and primary jurisdiction. Neither doctrine, however, supports the court's conclusion. Indeed, in opposing certiorari, Coca-

Cola did not even attempt to defend the Ninth Circuit's actual rationale. *See* Br. in Opp. 1, 6, 7, 15; *see also infra* p. 45.

1. By relying heavily on FDA's regulatory authority and assertedly "comprehensive regulation," Pet. App. 12a, the Ninth Circuit appeared to apply considerations that might be relevant in the context of a *field* preemption analysis, where courts are tasked with discerning whether "'the scope of a [federal] statute indicates that Congress intended federal law to occupy a field exclusively.'" *Kurns* v. *Railroad Friction Prods. Corp.*, 132 S. Ct. 1261, 1266 (2012) (quoting *Freightliner Corp.* v. *Myrick*, 514 U.S. 280, 287 (1995)) (alterations in *Kurns*). But field preemption is not the relevant analog in considering whether one federal statute impliedly repealed another federal statute. Rather, the relevant preemption counterpart is the strongest form of conflict preemption—"impossibility" preemption. *Wyeth*, 555 U.S. at 573. That standard, like the standard applicable in the implied-repeal context, requires the defendant to show an "irreconcilable conflict" between the allegedly conflicting statutes. *Silkwood* v. *Kerr-McGee Corp.*, 464 U.S. 238, 256 (1984). For the reasons set forth above, Coca-Cola does not come close to satisfying that "demanding" standard. *Wyeth*, 555 U.S. at 573.

In any event, the Ninth Circuit's analysis would be wrong even if field preemption principles applied. The Court has warned against too easily "infer[ring] preemption from the comprehensiveness of [agencies'] regulations." *Hillsborough Cnty., Fla.* v. *Automated Med. Labs., Inc.*, 471 U.S. 707, 717 (1985). "To infer pre-emption whenever an agency deals with a problem comprehensively is virtually tantamount to saying that whenever a federal agency decides to step into a field, its regulations will be exclusive." *Id.* This is precisely

what the Ninth Circuit purported to do in this case: Relying on FDA's supposed "comprehensive regulation" and little else, it concluded that "'the appropriate forum for [Pom's] complaints is the [FDA].'" Pet. App. 12a (alterations in original).

The Third Circuit's decision in *Holk* v. *Snapple Beverage Corp.* is instructive. 575 F.3d 329. Adhering to this Court's teachings in *English* v. *General Electric Co.*, 496 U.S. 72 (1990), and *Hillsborough County*, the Third Circuit properly expressed "reluctan[ce] to find field preemption predicated solely on the comprehensiveness of federal regulation." 575 F.3d at 338. After careful review of Congress' and FDA's relevant pronouncements, the court concluded that "neither Congress nor the FDA intended to occupy the fields of food and beverage labeling and juice products." *Id.* at 339. Other lower courts have reached the same conclusion,[7] as has the United States. U.S. Pet. Br. 10-11. Moreover, as discussed below, the premise that FDA has comprehensively regulated juice labels is incorrect. *See infra* pp. 47-49, 52-54.

2. The Ninth Circuit also invoked notions of agency deference, making repeated reference to FDA's "expertise" in juice labeling and concluding that "'the appropriate forum for [Pom's] complaints is the [FDA].'" Pet. App. 12a (alterations in original); *see id.* 8a (FDA's "apparent determination[s]"), 10a (FDA's "expert

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[7] *See Pom Wonderful LLC* v. *Ocean Spray Cranberries, Inc.*, 642 F. Supp. 2d 1112, 1123 (C.D. Cal. 2009); *Hitt* v. *Arizona Beverage Co.*, No. 08-cv-809, 2009 WL 449190, at *5 (S.D. Cal. Feb. 4, 2009); *Lockwood* v. *Conagra Foods, Inc.*, 597 F. Supp. 2d 1028, 1032 (N.D. Cal. 2009).

judgment[]"), 11a (same), 12a ("[T]he agency may act if it believes that a label in the market is deceptive"). The deference principles invoked by the Ninth Circuit—which underpin the separate doctrine of primary jurisdiction—are also inapposite here. Indeed, Coca-Cola did not seek dismissal on primary jurisdiction grounds.

First, because primary jurisdiction is grounded in principles of deference, it necessarily presupposes that the parties are able at least to apply to the agency for a ruling. *See Reiter* v. *Cooper*, 507 U.S. 258, 268 & n.3 (1993) (citing *Mitchell Coal & Coke Co.* v. *Pennsylvania R.R. Co.*, 230 U.S. 247, 267 (1913)). But FDA "does not accept formal petitions to take a discretionary enforcement action" and any enforcement decision by FDA "would not be subject to judicial review." U.S. Pet. Br. 15 (citing 21 C.F.R. § 10.30(k); *Heckler* v. *Chaney*, 470 U.S. 821, 837-838 (1985)). Against this backdrop, the Ninth Circuit's conclusion that "'the appropriate forum for [Pom's] complaint is the [FDA]'" is not so much an invocation of abstention as a declaration of abdication. Pet. App. 12a.[8]

Second, the primary jurisdiction doctrine permits a court "to enable a 'referral' to [an] agency ... to seek an administrative ruling" only under limited circumstanc-

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[8] Additionally, any dismissal under the primary jurisdiction doctrine must be *without* prejudice. *See Reiter*, 507 U.S. at 268-269 ("Referral of the issue to the administrative agency does not deprive the court of jurisdiction; it has discretion either to retain jurisdiction or, if the parties would not be unfairly disadvantaged, to dismiss the case without prejudice."). Here, however, the court of appeals affirmed judgment for Coca-Cola *with* prejudice. Pet. App. 14a.

es—i.e., where the relevant "claims ... *contain some issue within the special competence* of [the] administrative agency." *Reiter*, 507 U.S. at 268 (emphasis added). Pom's claim, however, arises under the Lanham Act, and its outcome is independent of the application or interpretation of the FDCA or FDA's regulations. JA 28a-30a. The Solicitor General properly acknowledged that FDA "does not administer the Lanham Act" and expressly disavows any "authority to resolve [Pom]'s claim of competitive injury due to a misleading label." U.S. Pet. Br. 14. This case thus lacks the core precondition of cases warranting administrative deference: the "issue" in dispute—whether Coca-Cola's product is misleading under the Lanham Act—is *not* "within the special competence of [the] agency." *Reiter*, 507 U.S. at 268; *see also Nader*, 426 U.S. at 305-306 (declining to apply primary jurisdiction where "[t]he standards to be applied ... are within the conventional competence of the courts, and the judgment of a technically expert body is not likely to be helpful in the application of th[o]se standards.").

Third, importing primary-jurisdiction-like principles into the preclusion context would perpetuate the needless doctrinal confusion that the Ninth Circuit's decision has already created. *See Watkins* v. *Vital Pharm., Inc.*, No. 12-cv-9374, 2013 WL 5972174, at *3 (C.D. Cal. Nov. 7, 2013) ("Although the precise issue before the court in *Pom Wonderful* was whether the FDCA barred the plaintiff's Lanham Act claim, courts have interpreted the decision as 'based on the idea of deference to the FDA' and 'implicitly relying on the primary jurisdiction doctrine.'"); *Won Kyung Hwang* v. *Ohso Clean, Inc.*, No. 12-cv-6355, 2013 WL 1632697, at *16, *18 (N.D. Cal. Apr. 16, 2013); *Ivie* v. *Kraft Foods Global, Inc.*, No. 12-cv-2554, 2013 WL 685372, at *6-7

(N.D. Cal. Feb. 25, 2013); *Astiana* v. *Hain Celestial Grp., Inc.*, 905 F. Supp. 2d 1013, 1015 (N.D. Cal. 2012); *All One God Faith, Inc.* v. *Hain Celestial Grp., Inc.*, No. 09-cv-3517, 2012 WL 3257660, at *9 (N.D. Cal. Aug. 8, 2012).

* * *

The unbounded scope of the court of appeals' decision magnifies its adverse impact. Under the Ninth Circuit's ruling, so long as products meet FDA's minimum requirements "as best [one] can tell," Pet. App. 9a, manufacturers can label them in any manner, without regard to whether their labeling deceives consumers and unfairly injures competitors. The ruling thus displaces even Lanham Act claims that allege, as Pom did in this case, that a manufacturer has *knowingly* used a label that is misleading. *See id.* 35a (quoting internal email admitting "a risk from a misleading standpoint as the product has less than 0.5% of pomegranate and blueberry juices" but deciding to "assume the risk."). Nothing in the Lanham Act, the FDCA, or FDA's regulations tolerates—much less dictates—such a result.

D. Coca-Cola's Misleading Product Does Not Comply With The FDCA And FDA's Regulations

In this Court, Coca-Cola has not defended the "regulatory authority" rationale employed by the Ninth Circuit. Instead, Coca-Cola has argued that the Lanham Act does not apply because its product label allegedly complies with FDA's juice-naming regulations. *See* Br. in Opp. 1, 6, 10, 12. For all of the reasons set forth above, application of the Lanham Act to Coca-Cola's misleading label is not precluded even if that label did fully comply with the FDCA and FDA's juice-

naming regulations because Coca-Cola cannot satisfy the "irreconcilable conflict" standard. But in any event, Coca-Cola's label does *not* comply.

1. Coca-Cola's product is misleading as a whole and thus violates the FDCA

FDA has cautioned that its juice-naming provision "does not relieve the manufacturer of the obligation to label the product in a truthful and nonmisleading manner." 58 Fed. Reg. at 2920.[9] *See supra* pp. 35-36. Consistent with this position, FDA has deemed misbranded under the FDCA's catch-all provision, 21 U.S.C. § 343(a)—and taken action against—juice products that seemingly comply with FDA's discrete labeling regulations but remain misleading in the aggregate. *See supra* pp. 37-38. In short, there is no compliance with the FDCA if a label is misleading in the aggregate.

That is the case here. Pom's complaint challenges Coca-Cola's presentation of its *entire* product as misleading, not merely discrete aspects of the label. *See* JA 61a, 26a. In this Court, Coca-Cola disaggregates certain components of its product's label—primarily, the common name and the font size used by Coca-Cola for certain required language on the label—and argues that Pom's claim should be precluded because those components, in isolation, allegedly comply with certain FDA regulations. *See, e.g.*, Br. in Opp. 5-6. But consumers see the entire label (along with the color of the juice, which Coca-Cola intentionally colors deep pur-

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[9] *See also id.* ("[F]or multiple-juice beverages that name one or more but not all of the juices [in the product's name], there is great potential for the label to misrepresent the contribution of the named juice to the product."); U.S. Pet. Br. 12 & n.3.

ple), not merely the product's name or strings of words in differing font sizes. Thus, even assuming that some elements of Coca-Cola's label did comply with narrow regulations addressing particular labeling requirements, such selective compliance would be irrelevant. So long as the label as a whole is misleading, it does not comply with 21 U.S.C. § 343(a) as interpreted by FDA, *see supra* pp. 35-38, and there is no reason—even under Coca-Cola's own theory—why Pom should be barred from pursuing its Lanham Act claim. *See also* 21 U.S.C. § 321(n) (inquiry into whether label is misleading must take into account failure to reveal facts material in light of representations suggested on label).

2. The misleading aspects of Coca-Cola's product are not in compliance with specific FDA regulations

In any event, Coca-Cola has not shown that the various misleading elements of its product comply with specific FDA regulations applicable to those elements.

Font Sizes. In its product label, Coca-Cola elected to use much smaller print for some of the words required to be part of the "name" of its product under FDA's regulations ("Flavored Blend of 5 Juices") than for the words in its product name that Coca-Cola wants customers to focus on ("Pomegranate" and "Blueberry"). Pet. App. 11a. In considering that aspect of Pom's challenge, the Ninth Circuit acknowledged that there is no FDA regulation on point. *See id.* ("If the FDA thought such a regulation were necessary 'to render [that information] likely to be read and understood by the ordinary individual,' it could have said so.'" (citing 21 U.S.C. § 343(f) (alteration in original)). And FDA itself confirms that "the FDCA and FDA have not specifically addressed 'how [Coca-Cola] presents

the words 'Pomegranate Blueberry' and 'Flavored Blend of 5 Juices' on the product's label.'" U.S. Pet. Br. 19 (quoting Pet. App. 10a).

Undeterred, Coca-Cola now argues that the "FDA has specifically addressed the font-size issue in 21 C.F.R. § 101.22(i)(1)(i)." Resp. Supp. Br. 3. That is doubly wrong.

First, § 101.22(i)(1)(i) applies only if "the food is one that is commonly expected to contain a characterizing food ingredient, e.g., strawberries in 'strawberry shortcake.'" 21 C.F.R. § 101.22(i)(1)(i). The food at issue here is a blend of juices consisting of "99.4% apple and grape juices, 0.3% pomegranate juice, 0.2% blueberry juice, and 0.1% raspberry juice." Pet. App. 2a. To the extent such a blend of juices is "commonly expected to contain a characterizing food ingredient," it surely is not pomegranate juice or blueberry juice.

Second, if § 101.22(i)(1)(i) is at all relevant, at most it addresses the font size of the single word "Flavored." *See* 21 C.F.R. § 101.22(i)(1)(i) ("[T]he name of the characterizing flavor [here, "Pomegranate Blueberry"] ... shall be immediately followed *by the word "flavored"* in letters not less than one-half the height of the letters in the name of the characterizing flavor" (emphasis added)).[10] It does not authorize Coca-Cola to shrink the words "Blend of 5 Juices" as it has done. That language is required to be included in the product's "common or usual name" by a different regulation, 21 C.F.R.

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[10] A product's "characterizing flavor(s)" includes any flavor that the producer elects to highlight as the primary flavor through labeling, advertising, or by other means. *See* 21 C.F.R. § 101.22(i).

§ 102.33(c), which addresses a product's basic nature—not added flavoring—and does not address the font size of the language it requires.

By attempting to insert § 101.22(i)(1)(i)'s provision into § 102.33(c), Coca-Cola ignores the different purposes of these two regulations. FDA stressed these distinct purposes in refusing to exempt juice products that must use the term "flavor" or "flavored" under § 101.22(i) from § 102.33's "common or usual name" requirement. *See* 58 Fed. Reg. at 2920. A commenter arguing for that exemption contended that use of the word "flavor" following the characterizing ingredient would "adequately inform[] the consumer in accordance with § 101.22." *Id.* But FDA refused to permit parties to omit the phrase "blend of —— other juices" required by § 102.33, noting that § 101.22 "informs the consumer when flavoring substances have been added to the product," while § 102.33 "describes other aspects of the basic nature of the product." *Id.*

The Product Name. Coca-Cola claims that the name of its product complies with FDA's juice-naming regulation set forth in 21 C.F.R. § 102.33(d). That regulation permits a product to be named after a juice that "is not the predominant juice" if the name of the product "[i]ndicate[s] that the named juice is present as a flavor or flavoring." 21 C.F.R. § 102.33(d)(1). But Coca-Cola's own contentions in this Court indicate that its product does not, in fact, comply with § 102.33(d) because the traces of pomegranate and blueberry juices in its product are not "present as a flavor or flavoring."

Coca-Cola's reliance on 21 C.F.R. § 101.22(i)(1)(i) demonstrates as much. That provision, which sets minimum font sizes for the mandatory disclosure that a food contains *added* natural flavoring, applies only

where "the food contains ... an amount of characterizing ingredient *insufficient to independently characterize the food*, or the food contains *no such ingredient*." 21 C.F.R. § 101.22(i)(1)(i) (emphases added). Coca-Cola's reliance on this provision is thus a telling admission that its product contains so little pomegranate and blueberry juice that those juices do *not* independently characterize the product. It is added "natural flavoring"[11]—not actual pomegranate and blueberry *juice*—that (allegedly) gives the product a pomegranate-blueberry flavor. Because pomegranate juice and blueberry juice are not "present as a flavor" as required by § 102.33(d), Coca-Cola cannot invoke that provision to show that its product's name complies with FDA's juice-naming regulations.

Notably, Coca-Cola does not invoke § 101.22(i)(1)(iii), which applies if a food "contains *both* a characterizing flavor *from the product whose flavor is simulated* and other natural flavor which simulates, resembles or reinforces the characterizing flavor" (emphasis added). That provision—not § 101.22(i)(1)(i)—would apply if Coca-Cola were relying on both the trace amounts of pomegranate and blueberry juice and added natural flavoring to generate the claimed flavor of the product. But if that provision were applicable, then Coca-Cola would not be in compliance with its requirement that "the name of the food shall be *immediately*

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[11] The term "natural flavor" (or "natural flavoring") is an FDA term of art that refers to certain substances, such as essential oils and extractives, which contain "flavoring constituents derived from" items like "fruit or fruit juice" and "whose significant function in food is flavoring rather than nutritional." 21 C.F.R. § 101.22(a)(3).

followed by the words 'with other natural flavor.'" 21 C.F.R. § 101.22(i)(1)(iii) (emphasis added). Those words appear on Coca-Cola's label only after the words "From Concentrate With Added Ingredient," which themselves are separated from the phrase "Pomegranate Blueberry Flavored Blend of 5 Juices" by an empty line. *See* JA 38a; CA ER 108, 112.

Coca-Cola's own arguments in this case thus cast significant doubt on whether the miniscule quantities of pomegranate juice and blueberry juice in its product suffice to provide the product's "flavor or flavoring." And even if they did, it would still remain far from clear that Coca-Cola could rely on §102.33(d)(1) in light of the restriction imposed by 21 C.F.R. § 102.5(b), which mandates that

> [t]he common or usual name of a food shall include the percentage(s) of any characterizing ingredient(s) or component(s) when the proportion of such ingredient(s) or component(s) in the food has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present in an amount greater than is actually the case.[12]

21 C.F.R. § 102.5(b). Pomegranate juice and blueberry juice are far more expensive than the juices that comprise over 99% of Coca-Cola's "Pomegranate Blueberry" juice product, Pet. App. 2a, and the proportion of

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[12] *See* 58 Fed. Reg. at 2920, 2921 (noting the application of § 102.5(b) to multiple-juice blends).

pomegranate and blueberry juice obviously has a bearing on consumer acceptance of Coca-Cola's product, JA 24a-26a. Yet, Coca-Cola's label does not include—or even hint at—the trivial percentage of pomegranate and blueberry juice in the product.

The Vignette. The fruit "vignette" on Coca-Cola's label is also misleading. It prominently features a large pomegranate that is placed in front of an apple of roughly the same size. *See* JA 38a. It also features outsized blueberries that sit in front of the grapes pictured on the label. Nothing in this display suggests that pomegranate and blueberry juice together make up just 0.5% of the product, while apple and grape juice make up over 99%. Although FDA discussed fruit vignettes in the 1993 rulemaking (*see* 58 Fed. Reg. at 2921-2922), Coca-Cola has never pointed to a regulation "authorizing" its misleading vignette.

II. Congress Could Not Have Intended The Result Reached By The Ninth Circuit Or Urged By Coca-Cola

A. FDA Lacks The Resources To Regulate False And Misleading Food Labels

Congress could not have intended to leave all regulation of misleading food labels to FDA, which lacks the resources to handle that critical task. As Congress has long understood, FDA woefully lacks the resources necessary to police misleading food labels. In *Wyeth*, this Court noted that the "FDA has limited resources" to conduct even what might be its most critical mission: to ensure the safety and effectiveness of pharmaceuticals. 555 U.S. at 578 & n.11. For this reason, even in that area of significant scientific complexity, FDA "long maintained that state law offers an additional, and im-

portant, layer of consumer protection that complements FDA regulation." *Id.* at 579.

In the realm of food labeling, the agency's resources are even more markedly inadequate to its mission. As the Government Accountability Office explained in a 2008 report, FDA's efforts to regulate food labeling leave significant gaps. *See* U.S. Gov't Accountability Office, GAO 08-597, *Food Labeling: FDA Needs to Better Leverage Resources, Improve Oversight, and Effectively Use Available Data to Help Consumers Select Healthy Foods* (2008) ("GAO Report"), *available at* http://www.gao.gov/assets/290/280466.pdf. The Report's overall conclusion was summarized as follows: "FDA has limited assurance that domestic and imported foods comply with food labeling requirements, such as those prohibiting false or misleading labeling." *Id.* at 5.

More specifically, the Report explained that: "FDA has reported that limited resources and authorities significantly challenge its efforts to carry out food safety responsibilities—challenges that also impact efforts to administer and enforce labeling requirements." GAO Report 6. In 2007, over 65,000 firms were subject to FDA's food regulations. *See id.* at 51, tbl. 9. These firms, of course, manufacture countless numbers of different food products. But from 2005 to 2007, the portion of the FDA Office of Nutrition, Labeling, and Dietary Supplements "dedicated to food labeling activities" had an annual budget of only "$1.1 million to $1.3 million" and had only "from 9.0 to 10.5" full-time equivalent employees. *Id.* at 7. From 1998 through 2006, FDA obtained only *two* injunctions against firms for food-related mislabeling. *See id.* at 22. For the most part, the agency simply issued warning letters, if it did anything at all. *See id.* at 18-21. Indeed, FDA has

acknowledged that it generally does not even attempt to police misleading food labels:

> [A]ccording to FDA officials, the agency generally does not address misleading food labeling because it lacks the resources to conduct the substantive, empirical research on consumer perceptions that it believes it would need to legally demonstrate that a label is misleading[.]

Id. at 30.

FDA's inadequate resources create a gap that the Lanham Act plays a crucial role in filling. The threat of liability under the Lanham Act provides a substantial economic disincentive vital to offsetting the monetary incentives that exist for certain producers to create inaccurate or misleading labeling. Indeed, in the hearings leading up to enactment of the NLEA, Congress heard from the advertising industry that the danger of a Lanham Act suit is a "step" in "deciding" whether a consumer will be misled by a food label or advertisement. *See* 1990 Senate Hearing, at 74 ("There is also the Lanham Act, which says that if you ... create a false impression about your product versus some other product, you can be sued by other companies that say that this is injuring them. There have been a number of food Lanham Act suits where millions of dollars of penalties have been brought forward."). There is no reason to believe Congress intended to eliminate this essential constraint.

B. The Ninth Circuit's Reasoning Would Apply To A Range Of Other Regulatory Regimes

The Ninth Circuit's reasoning reaches beyond food labeling regulated by FDA. It has been applied to other products regulated by FDA. *See Astiana*, 905 F.

Supp. 2d at 1014-1017 (FDA's authority to regulate cosmetics barred state-law mislabeling challenge to cosmetics labeled "all natural," "pure natural," and "pure, natural & organic"). And it extends to other federal statutes that empower other agencies to police false and misleading statements through regulation. Indeed, one court has already applied the Ninth Circuit's decision to preclude a Lanham Act claim challenging the labeling of personal care and cosmetic products as "organic" in light of the USDA's regulation of such products under the Organic Food Products Act of 1990. *See All One God Faith*, 2012 WL 3257660, at *1-11.

Perhaps most significantly, the FTC is broadly charged with preventing "unfair or deceptive acts or practices in or affecting commerce." 15 U.S.C. § 45(a)(1)-(2). To that end, the FTC has issued regulatory guides for a variety of sectors, from plant nurseries to auto parts, from jewelry to private vocational and distance schools. *See* 16 C.F.R. §§ 18.0-18.8, 20.0-20.3, 23.0-23.26, 254.0-254.7. Under the Ninth Circuit's reasoning, the FTC's expansive regulatory authority would preclude a Lanham Act suit against demonstrably misleading statements in any regulated field.

Congress enacted the prohibition on false advertising in the Lanham Act to prevent competitive injury based on misleading product claims. It has made clear that robust private enforcement of that provision is necessary to further "the public policy of deterring acts of unfair competition." S. Rep. No. 100-515, at 38 (1988), *reprinted in* 1988 U.S.C.C.A.N. 5577, 5603. That purpose is directly served in this case. Coca-Cola was not required to use a misleading label—it did so to unfairly lure customers away from Pom. Nothing in the FDCA or FDA's regulations bar Pom's claim. The

Ninth Circuit's contrary conclusion finds no basis in this Court's precedents and would significantly undermine the Lanham Act. Where Congress has enacted two statutes that apply to the same underlying conduct, it is the role of the courts to apply both of those laws to the fullest extent possible. Here, both the Lanham Act and the FDCA can and should be given effect.

CONCLUSION

The judgment should be reversed.

Respectfully submitted.

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FEBRUARY 2014

APPENDICES

15 U.S.C. § 1116: Injunctive relief

(a) Jurisdiction; service

The several courts vested with jurisdiction of civil actions arising under this chapter shall have power to grant injunctions, according to the principles of equity and upon such terms as the court may deem reasonable, to prevent the violation of any right of the registrant of a mark registered in the Patent and Trademark Office or to prevent a violation under subsection (a), (c), or (d) of section 1125 of this title. Any such injunction may include a provision directing the defendant to file with the court and serve on the plaintiff within thirty days after the service on the defendant of such injunction, or such extended period as the court may direct, a report in writing under oath setting forth in detail the manner and form in which the defendant has complied with the injunction. Any such injunction granted upon hearing, after notice to the defendant, by any district court of the United States, may be served on the parties against whom such injunction is granted anywhere in the United States where they may be found, and shall be operative and may be enforced by proceedings to punish for contempt, or otherwise, by the court by which such injunction was granted, or by any other United States district court in whose jurisdiction the defendant may be found.

* * *

15 U.S.C. § 1117: Recovery for violation of rights

(a) Profits; damages and costs; attorney fees

When a violation of any right of the registrant of a mark registered in the Patent and Trademark Office, a violation under section 1125(a) or (d) of this title, or a willful violation under section 1125(c) of this title, shall have been established in any civil action arising under this chapter, the plaintiff shall be entitled, subject to the provisions of sections 1111 and 1114 of this title, and subject to the principles of equity, to recover (1) defendant's profits, (2) any damages sustained by the plaintiff, and (3) the costs of the action. The court shall assess such profits and damages or cause the same to be assessed under its direction. In assessing profits the plaintiff shall be required to prove defendant's sales only; defendant must prove all elements of cost or deduction claimed. In assessing damages the court may enter judgment, according to the circumstances of the case, for any sum above the amount found as actual damages, not exceeding three times such amount. If the court shall find that the amount of the recovery based on profits is either inadequate or excessive the court may in its discretion enter judgment for such sum as the court shall find to be just, according to the circumstances of the case. Such sum in either of the above circumstances shall constitute compensation and not a penalty. The court in exceptional cases may award reasonable attorney fees to the prevailing party.

* * *

15 U.S.C. § 1125: False designations of origin, false descriptions, and dilution forbidden

(a) Civil action

(1) Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which—

> (A) is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person, or
>
> (B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities,

shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

(2) As used in this subsection, the term "any person" includes any State, instrumentality of a State or employee of a State or instrumentality of a State acting in his or her official capacity. Any State, and any such instrumentality, officer, or employee, shall be subject to the provisions of this chapter in the same manner and to the same extent as any nongovernmental entity.

(3) In a civil action for trade dress infringement under this chapter for trade dress not registered on the principal register, the person who asserts trade dress pro-

tection has the burden of proving that the matter sought to be protected is not functional.

* * *

15 U.S.C. § 1127: Construction and definitions; intent of chapter

* * *

The intent of this chapter is to regulate commerce within the control of Congress by making actionable the deceptive and misleading use of marks in such commerce; to protect registered marks used in such commerce from interference by State, or territorial legislation; to protect persons engaged in such commerce against unfair competition; to prevent fraud and deception in such commerce by the use of reproductions, copies, counterfeits, or colorable imitations of registered marks; and to provide rights and remedies stipulated by treaties and conventions respecting trademarks, trade names, and unfair competition entered into between the United States and foreign nations.

21 U.S.C. § 321: Definitions; generally

* * *

(f) The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

* * *

(n) If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determin-

ing whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.

* * *

21 U.S.C. § 331: Prohibited acts

The following acts and the causing thereof are prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, tobacco product, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

* * *

(g) The manufacture within any Territory of any food, drug, device, tobacco product, or cosmetic that is adulterated or misbranded.

* * *

21 U.S.C. § 333: Penalties

(a) Violation of section 331 of this title; second violation; intent to defraud or mislead

(1) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.

(2) Notwithstanding the provisions of paragraph (1) of this section, if any person commits such a violation after a conviction of him under this section has become final, or commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.

* * *

21 U.S.C. § 337: Proceedings in name of United States; provision as to subpoenas

(a) Except as provided in subsection (b) of this section, all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

(b)(1) A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 341, 343(b), 343(c), 343(d), 343(e), 343(f), 343(g), 343(h), 343(i), 343(k), 343(q), or

343(r) of this title if the food that is the subject of the proceedings is located in the State.

(2) No proceeding may be commenced by a State under paragraph (1)—

(A) before 30 days after the State has given notice to the Secretary that the State intends to bring such proceeding,

(B) before 90 days after the State has given notice to the Secretary of such intent if the Secretary has, within such 30 days, commenced an informal or formal enforcement action pertaining to the food which would be the subject of such proceeding, or

(C) if the Secretary is diligently prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled the informal or formal enforcement action pertaining to such food.

In any court proceeding described in subparagraph (C), a State may intervene as a matter of right.

21 U.S.C. § 343: Misbranded food

A food shall be deemed to be misbranded—

(a) False or misleading label

If (1) its labeling is false or misleading in any particular, or (2) in the case of a food to which section 350 of this title applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 350(b)(2) of this title.

* * *

(f) Prominence of information on label

If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

* * *

(i) Label where no representation as to definition and standard of identity

Unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient and if the food purports to be a beverage containing vegetable or fruit juice, a statement with appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice contained in the food; except that spices, flavorings, and colors not required to be certified under section 379e(c) of this title unless sold as spices, flavorings, or such colors, may be designated as spices, flavorings, and colorings without naming each. To the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

* * *

21 U.S.C. § 343-1: National uniform nutrition labeling

(a) Except as provided in subsection (b) of this section, no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—

(1) any requirement for a food which is the subject of a standard of identity established under section 341 of this title that is not identical to such standard of identity or that is not identical to the requirement of section 343(g) of this title, except that this paragraph does not apply to a standard of identity of a State or political subdivision of a State for maple syrup that is of the type required by sections 341 and 343(g) of this title,

(2) any requirement for the labeling of food of the type required by section 343(c), 343(e), 343(i)(2), 343(w), or 343(x) of this title that is not identical to the requirement of such section, except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 343(c) of this title and that is applicable to maple syrup,

(3) any requirement for the labeling of food of the type required by section 343(b), 343(d), 343(f), 343(h), 343(i)(1), or 343(k) of this title that is not identical to the requirement of such section, except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 343(h)(1) of this title and that is applicable to maple syrup,

(4) any requirement for nutrition labeling of food that is not identical to the requirement of section

343(q) of this title, except that this paragraph does not apply to food that is offered for sale in a restaurant or similar retail food establishment that is not part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership of the locations) and offering for sale substantially the same menu items unless such restaurant or similar retail food establishment complies with the voluntary provision of nutrition information requirements under section 343(q)(5)(H)(ix) of this title, or

(5) any requirement respecting any claim of the type described in section 343(r)(1) of this title, made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title, except a requirement respecting a claim made in the label or labeling of food which is exempt under section 343(r)(5)(B) of this title.

Paragraph (3) shall take effect in accordance with section 6(b) of the Nutrition Labeling and Education Act of 1990.

* * *

21 U.S.C. § 343-1 Note (Construction of Pub. L. No. 101-535)

Pub. L. 101–535, § 6(c), Nov. 8, 1990, 104 Stat. 2364, provided that:

(1) The Nutrition Labeling and Education Act of 1990 [Pub. L. 101–535, see Short Title of 1990 Amendment note set out under section 301 of this title] shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under section

403A of the Federal Food, Drug, and Cosmetic Act [this section].

(2) The amendment made by subsection (a) [enacting this section] and the provisions of subsection (b) [set out as a note above] shall not be construed to apply to any requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food.

(3) The amendment made by subsection (a), the provisions of subsection (b) and paragraphs (1) and (2) of this subsection shall not be construed to affect preemption, express or implied, of any such requirement of a State or political subdivision, which may arise under the Constitution, any provision of the Federal Food, Drug, and Cosmetic Act [this chapter] not amended by subsection (a), any other Federal law, or any Federal regulation, order, or other final agency action reviewable under chapter 7 of title 5, United States Code."

21 C.F.R. § 101.18: Misbranding of food

* * *

(b) The labeling of a food which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such food in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

* * *

21 C.F.R. § 101.22: Foods; labeling of spices, flavorings, colorings and chemical preservatives

(a) ...

(3) The term *natural flavor* or *natural flavoring* means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional. Natural flavors include the natural essence or extractives obtained from plants listed in §§ 182.10, 182.20, 182.40, and 182.50 and part 184 of this chapter, and the substances listed in § 172.510 of this chapter.

* * *

(i) If the label, labeling, or advertising of a food makes any direct or indirect representations with respect to the primary recognizable flavor(s), by word, vignette, e.g., depiction of a fruit, or other means, or if for any other reason the manufacturer or distributor of a food wishes to designate the type of flavor in the food other than through the statement of ingredients, such flavor shall be considered the characterizing flavor and shall be declared in the following way:

(1) If the food contains no artificial flavor which simulates, resembles or reinforces the characterizing flavor, the name of the food on the principal display panel or panels of the label shall be accompanied by the common or usual name of the charac-

terizing flavor, e.g., "vanilla", in letters not less than one-half the height of the letters used in the name of the food, except that:

(i) If the food is one that is commonly expected to contain a characterizing food ingredient, e.g., strawberries in "strawberry shortcake", and the food contains natural flavor derived from such ingredient and an amount of characterizing ingredient insufficient to independently characterize the food, or the food contains no such ingredient, the name of the characterizing flavor may be immediately preceded by the word "natural" and shall be immediately followed by the word "flavored" in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g., "natural strawberry flavored shortcake," or "strawberry flavored shortcake".

(ii) If none of the natural flavor used in the food is derived from the product whose flavor is simulated, the food in which the flavor is used shall be labeled either with the flavor of the product from which the flavor is derived or as "artificially flavored."

(iii) If the food contains both a characterizing flavor from the product whose flavor is simulated and other natural flavor which simulates, resembles or reinforces the characterizing flavor, the food shall be labeled in accordance with the introductory text and paragraph (i)(1)(i) of this section and the name of the food shall be immediately followed by the words "with other natural flavor" in letters not less than one-half

the height of the letters used in the name of the characterizing flavor.

* * *

21 C.F.R. § 102.5: General principles

* * *

(b) The common or usual name of a food shall include the percentage(s) of any characterizing ingredient(s) or component(s) when the proportion of such ingredient(s) or component(s) in the food has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present in an amount greater than is actually the case. The following requirements shall apply unless modified by a specific regulation in subpart B of this part.

(1) The percentage of a characterizing ingredient or component shall be declared on the basis of its quantity in the finished product (i.e., weight/weight in the case of solids, or volume/volume in the case of liquids).

(2) The percentage of a characterizing ingredient or component shall be declared by the words "containing (or contains) ___ percent (or %) _____" or "___ percent (or %) _____" with the first blank filled in with the percentage expressed as a whole number not greater than the actual percentage of the ingredient or component named and the second blank filled in with the common or usual name of the ingredient or component. The word "containing" (or "contains"), when used, shall appear on a line im-

mediately below the part of the common or usual name of the food required by paragraph (a) of this section. For each characterizing ingredient or component, the words "___ percent or %) _____" shall appear following or directly below the word "containing" (or contains), or directly below the part of the common or usual name of the food required by paragraph (a) of this section when the word "containing" (or contains) is not used, in easily legible boldface print or type in distinct contrast to other printed or graphic matter, and in a height not less than the larger of the following alternatives:

(i) Not less than one-sixteenth inch in height on packages having a principal display panel with an area of 5 square inches or less and not less than one-eighth inch in height if the area of the principal display panel is greater than 5 square inches; or

(ii) Not less than one-half the height of the largest type appearing in the part of the common or usual name of the food required by paragraph (a) of this section.

* * *

21 C.F.R. § 102.33: Beverages that contain fruit or vegetable juice

(a) For a carbonated or noncarbonated beverage that contains less than 100 percent and more than 0 percent fruit or vegetable juice, the common or usual name shall be a descriptive name that meets the requirements of § 102.5(a) and, if the common or usual name uses the word "juice," shall include a qualifying term

such as "beverage," "cocktail," or "drink" appropriate to advise the consumer that the product is less than 100 percent juice (e.g., "diluted grape juice beverage" or "grape juice drink").

(b) If the product is a diluted multiple-juice beverage or blend of single-strength juices and names, other than in the ingredient statement, more than one juice, then the names of those juices, except in the ingredient statement, must be in descending order of predominance by volume unless the name specifically shows that the juice with the represented flavor is used as a flavor (e.g., raspberry-flavored apple and pear juice drink). In accordance with § 101.22(i)(1)(iii) of this chapter, the presence of added natural flavors is not required to be declared in the name of the beverage unless the declared juices alone do not characterize the product before the addition of the added flavors.

(c) If a diluted multiple-juice beverage or blend of single-strength juices contains a juice that is named or implied on the label or labeling other than in the ingredient statement (represented juice), and also contains a juice other than the named or implied juice (nonrepresented juice), then the common or usual name for the product shall indicate that the represented juice is not the only juice present (e.g., "Apple blend; apple juice in a blend of two other fruit juices.")

(d) In a diluted multiple-juice beverage or blend of single-strength juices where one or more, but not all, of the juices are named on the label other than in the ingredient statement, and where the named juice is not the predominant juice, the common or usual name for the product shall:

(1) Indicate that the named juice is present as a flavor or flavoring (e.g., "Raspcranberry"; raspberry and cranberry flavored juice drink); or

(2) Include the amount of the named juice, declared in a 5–percent range (e.g., Raspcranberry; raspberry and cranberry juice beverage, 10– to 15–percent cranberry juice and 3– to 8–percent raspberry juice). The 5–percent range, when used, shall be declared in the manner set forth in § 102.5(b)(2).

(e) The common or usual name of a juice that has been modified shall include a description of the exact nature of the modification (e.g., "acid-reduced cranberry juice," "deflavored, decolored grape juice").

(f) If the product is a beverage that contains a juice whose color, taste, or other organoleptic properties have been modified to the extent that the original juice is no longer recognizable at the time processing is complete, or if its nutrient profile has been diminished to a level below the normal nutrient range for the juice, then the source fruits or vegetables from which the modified juice was derived may not be depicted on the label by vignette or other pictorial representation.

(g)(1) If one or more juices in a juice beverage is made from concentrate, the name of the juice must include a term indicating that fact, such as "from concentrate," or "reconstituted." Such terms must be included in the name of each individual juice or it may be stated once adjacent to the product name so that it applies to all the juices, (e.g., "cherry juice (from concentrate) in a blend of two other juices" or "cherry juice in a blend of 2 other juices (from concentrate)"). The term shall be in a type size no less than one-half the height of the letters in the name of the juice.

(2) If the juice is 100 percent single species juice consisting of juice directly expressed from a fruit or vegetable whose Brix level has been raised by the addition of juice concentrate from the same fruit or vegetable, the name of the juice need not include a statement that the juice is from concentrate. However, if water is added to this 100 percent juice mixture to adjust the Brix level, the product shall be labeled with the term "from concentrate" or "reconstituted."

RESPONDENT'S BRIEF

RECORD AND BRIEFS

Supreme Court, U.S.
FILED
MAR 26 2014
OFFICE OF THE CLERK

No. 12-761

IN THE

Supreme Court of the United States

POM WONDERFUL LLC,

Petitioner,

v.

THE COCA-COLA COMPANY,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

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QUESTION PRESENTED

Whether a juice manufacturer that employs a juice name and label authorized by a nationally-uniform standard under the Federal Food, Drug, and Cosmetic Act ("FDCA") and the Nutrition Labeling and Education Act of 1990 ("NLEA"), is subject to suits by private plaintiffs under section 43(a) of the Lanham Act that seek to impose standards different from the FDCA/NLEA standard.

RULE 29.6 STATEMENT

Respondent's Rule 29.6 Statement appears in the Brief in Opposition at ii.

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STATUTES AND REGULATIONS INVOLVED

Relevant provisions of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.*; the Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (1990); FDA's regulations, 21 C.F.R. pts. 101 & 102; and the Lanham Act, 15 U.S.C. §§ 1051 *et seq.*, are set forth in the Appendix, *infra*.

INTRODUCTION

In this case, a private litigant invoking the Lanham Act seeks to disrupt the national uniformity Congress has required in the naming and labeling of food and juice products. In enacting the Federal Food, Drug and Cosmetic Act ("FDCA"), Congress foreclosed any private right of action to enforce the statute's provisions, and in enacting the Nutrition Labeling and Education Act of 1990 ("NLEA"), Congress included an express preemption provision foreclosing state-law suits that might seek to impose naming or labeling standards that are not identical to enumerated standards authorized by the FDCA. That provision, tellingly entitled "National Uniform Nutrition Labeling," was intended to enable food and juice manufacturers to choose a single nationwide name and label for certain products, without facing the burdens and inefficiencies that would result if private plaintiffs across the country could impose their own idiosyncratic naming and labeling standards, as petitioner seeks to do here.

To be sure, Congress expressly preempted only suits under *state law*, and was silent as to suits under *federal* laws like the Lanham Act. But this Court has long held that a specific federal law (here, the FDCA/NLEA) may narrow the scope of a general federal law (here, the Lanham Act) even if Congress

has not expressly stated as much. The Court has instead discerned Congress's intent to narrow the scope of the general law from the specific law's text, structure, and purpose, see, *e.g.*, *Elgin* v. *Dep't of the Treasury*, 132 S. Ct. 2126, 2133 (2012)—just as in any statutory-interpretation case where Congress has failed to address the precise issue that later arises.

Congress's intent to preclude private Lanham Act suits under the circumstances here is evident, and it would be anomalous to allow a Lanham Act suit that poses the same threat to national uniformity as the state-law suits that Congress expressly preempted. The FDCA/NLEA and its implementing regulations allow a juice manufacturer like respondent to name its product "POMEGRANATE BLUEBERRY FLAVORED BLEND OF 5 JUICES ..." so as to indicate the presence of minority juices (here, pomegranate and blueberry) through the words "Flavored Blend Of 5 Juices." And the FDCA requires the phrase "Flavored Blend Of 5 Juices" to appear only with "such conspicuousness ... as to render it likely to be read and understood by the ordinary individual." If private plaintiffs could invoke the Lanham Act to deem respondent's name or label misleading, a patchwork of requirements would result, varying by state and jury. One plaintiff might insist that the predominant components (apple and grape) be included in the name; another might demand identification of the percentage contribution of each component; and a third might argue that the juice should be named *only* by the predominant components. Likewise, one plaintiff might seek to require that "Flavored Blend Of 5 Juices" be three-quarters rather than half the height of the words in the earlier part of the juice's name; a second might insist on equal height; a third might demand equal height and bold lettering. And so on.

This is not the regime of "National Uniform Nutrition Labeling" that Congress envisioned and enacted.

The United States correctly rejects (Br. 11-12) petitioner's argument that a specific federal law may never impliedly narrow a general one, and agrees (Br. 12-23) with respondent that petitioner's Lanham Act challenge to the name of respondent's juice is precluded. But the United States errs (Br. 23-33) in ignoring the force of the NLEA's express "national uniform[ity]" provision insofar as petitioner's challenge to the *non*-naming aspects of respondent's juice is concerned. While recognizing (Br. 20) that the express preemption provision distinguishes this case from *Wyeth* v. *Levine*, 555 U.S. 555 (2009), the United States incorrectly declines (Br. 25) to draw any inference from that provision regarding Congress's intent to preclude private Lanham Act suits that pose the same threat as state-law suits to national uniformity. Congress viewed *all* state-law requirements "not identical" to those under the FDCA as within the scope of the NLEA's preemption clause. It is thus inconsistent with Congress's intent to ask case-by-case, as the United States would (Br. 30), whether a Lanham Act plaintiff's particular proposed non-identical requirements would "tend to *reinforce*, not undo, the [FDCA's] statutory and regulatory requirements." And in assuming that Congress would welcome private efforts to heighten the federal standard, the United States conspicuously omits to note FDA's express recognition in the wake of the NLEA that stringency is not to be achieved at the cost of national uniformity:

> [O]ne of the goals of the 1990 amendments is national uniformity in certain aspects of food labeling, so that the food industry can market

> its products efficiently in all 50 States in a cost-effective manner. Thus, in enacting the 1990 amendments, Congress decided that even though Federal requirements may preempt more restrictive State requirements in certain instances, the net benefits from national uniformity in these aspects of the food label outweigh the loss in consumer protection that may occur as a result.

58 Fed. Reg. 2462, 2462 (Jan. 6, 1993) (internal citation omitted).

The FDCA provisions and FDA regulations, especially when interpreted against the backdrop of Congress's national-uniformity goal, authorize the name and label of respondent's product. Respondent acted reasonably in complying with those provisions and regulations. Petitioner's proposed regime allowing private Lanham Act challenges to that name and label interferes with Congress's intent. The judgment of the court of appeals should be affirmed.

STATEMENT

A. Statutory And Regulatory Background

1. The FDCA And NLEA

Congress enacted the FDCA in 1938 and amended it, as relevant here, in 1990 through the NLEA. Contrary to petitioner's description (Br. 6-7), the FDCA's food provisions do not rest solely on a purpose to protect public health and safety; they additionally "promote honesty and fair dealing in the interest of consumers." 21 U.S.C. § 341. The FDCA expressly reserves enforcement to the United States and bars private causes of action. See 21 U.S.C. § 337(a) ("[A]ll such proceedings for the enforcement, or to restrain

violations, of this chapter shall be by and in the name of the United States."). See also *id.* § 337(b) (granting limited enforcement rights to the States).[1]

FDCA § 403 prescribes circumstances under which "[a] food shall be deemed to be misbranded." 21 U.S.C. § 343. See also *id.* §§ 321(n) (a food can be "alleged to be misbranded because the labeling ... is misleading"); 321(f) ("food" includes "drink"). For example, a food is misbranded "[u]nless its label bears ... the common or usual name of the food, if any there be," *id.* § 343(i)(1), or "[i]f any word, statement, or other information required by or under authority of this chapter to appear on the label ... is not prominently placed thereon with such conspicuousness (as compared with other words ...) ... as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use," *id.* § 343(f).

FDA has adopted implementing regulations, including 21 C.F.R. § 102.33, which prescribes requirements for the name of a fruit-juice beverage that contains a "blend of single-strength juices." That regulation provides, *inter alia*, that the name need not include the names of those juices "in descending order of predominance by volume [if] the name specifically shows that the juice with the represented flavor is used as a flavor." *Id.* § 102.33(b). Thus, a juice blend that contains more apple and pear than raspberry need not be named "apple, pear, and raspberry juice drink," and may instead be named "raspberry-flavored

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[1] FDA may enforce the FDCA's provisions through a variety of administrative, civil, and criminal tools. See, *e.g.*, 21 U.S.C. §§ 336 (warning letters); 332 (civil judicial proceedings seeking injunction); 334(a) (civil judicial proceedings seeking seizure); 333(a) (imprisonment or fines).

apple and pear juice drink." *Ibid.* Indeed, the regulation provides that not all of the juice components need even be included in the name, so long as the name "indicate[s] that the represented juice is not the only juice present (e.g., 'Apple blend; apple juice in a blend of two other fruit juices.')." *Id.* § 102.33(c). And a juice that is included in the name may be a minority component, so long as the name "(1) [i]ndicate[s] that the named juice is present as a flavor or flavoring (e.g., 'Raspcranberry'; raspberry and cranberry flavored juice drink); or (2) [i]nclude[s] the amount of the named juice, declared in a 5-percent range ...." *Id.* § 102.33(d).[2] The concept of allowing the name to include a minority component followed by "flavored" is not unique to fruit-juice beverages but applies also to other foods. For example, a version of strawberry shortcake that contains very few actual strawberries may be named "'strawberry flavored shortcake.'" 21 C.F.R. § 101.22(i)(1)(i).

Other FDA regulations amplify FDCA § 403(f) regarding the "conspicuousness" of information on the label. For example, where a "food" (which, as noted, includes "drink") contains a "natural flavor which simulates, resembles or reinforces the characterizing flavor," FDA has provided that the label need not identify the flavor that "simulates, resembles or reinforces," but instead may set forth the name of "the characterizing flavor" if "immediately followed by the words 'with other natural flavor' in letters not less than one-half the height of the letters used in the

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[2] FDA has regulated the names and labels of fruit-juice beverages since at least 1967. See 56 Fed. Reg. 30452, 30452-53 (July 2, 1991) (recounting history).

name of the characterizing flavor." 21 C.F.R. § 101.22(i)(1)(iii).

The NLEA amended the FDCA by, *inter alia*, adding a provision entitled "National Uniform Nutrition Labeling." NLEA § 6 (codified in part at 21 U.S.C. § 343-1). As codified, this clause provides that "no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce ... any requirement for the labeling of food of the type required by section ... 343(f), ... [or] 343(i)(1) ... of this title that is not identical to the requirement of such section ...." 21 U.S.C. § 343-1(a)(3).

Congress provided that § 343-1(a)(3) would become effective only after, *first*, completion of a study "whether [the enumerated FDCA] sections and regulations adequately implement the purposes of such sections," NLEA § 6(b)(1)(B), and *second*, FDA's publication of a "list of [FDCA] sections which are adequately being implemented," *id.* § 6(b)(3)(B). The Institute of Medicine performed the study and reported, *inter alia*, that 21 U.S.C. §§ 343(f) and 343(i)(1) were adequately implemented. See Inst. of Medicine, *Food Labeling: Toward National Uniformity* 102, 113 (1992). FDA concurred, 58 Fed. Reg. 2470, 2473-74 (Jan. 6, 1993), thus making the preemption clause effective as to State requirements that are "not identical" to these FDCA subsections.

2. The Lanham Act

Congress enacted the Lanham Act in 1946 and amended its § 43(a) most recently in 1988, Pub. L. No. 100-667, § 132, 102 Stat. 3935, 3946 (1988). Section 43(a) is not specific to foods, but rather speaks broadly of "any goods or services, or any container for goods."

15 U.S.C. § 1125(a)(1). It provides a civil cause of action to an entity that is injured by another's "false or misleading description" or "representation" in connection with "goods or services." *Ibid.* Only business entities, not consumers, may sue under this provision. *Lexmark Int'l, Inc.* v. *Static Control Components, Inc.*, 572 U.S.___ (2014) (slip op. at 13, 22).

B. Factual Background

Coca-Cola's Minute Maid® division markets a 100% juice product that contains about 99.4% apple and grape juices, 0.3% pomegranate juice, 0.2% blueberry juice, and 0.1% raspberry juice. Pet. App. 2a. The largest feature on the front label is a "vignette" depicting half an apple, half a pomegranate, three blueberries, three grapes, and two raspberries. JA 38a. Below the vignette appears the word "POMEGRANATE"; below that in identical font size the word "BLUEBERRY"; below that in slightly smaller font size (but more than half the height of "POMEGRANATE") the words "FLAVORED BLEND OF 5 JUICES"; below that in slightly smaller font size (but again, more than half the height of "POMEGRANATE") the words "FROM CONCENTRATE WITH ADDED INGREDIENTS"; and below that in the same font size the words "AND OTHER NATURAL FLAVORS." *Ibid.*

The back label lists the beverage's ingredients in descending order by volume, beginning: "APPLE, GRAPE AND POMEGRANATE JUICES FROM CONCENTRATE, FRUIT AND VEGETABLE JUICES (FOR COLOR), BLUEBERRY JUICE FROM CONCENTRATE, NATURAL FLAVORS,

RASPBERRY JUICE FROM CONCENTRATE ...." JA 39a.[3]

C. Proceedings Below

1. Pom, which markets pomegranate juice and pomegranate juice blends, JA 58a; Pet. App. 1a, sued Coca-Cola in the U.S. District Court for the Central District of California, asserting, *inter alia*, a claim under Lanham Act § 43(a). Pom centrally alleged:

> [T]he main ingredients in Coca Cola's Pomegranate Blueberry Product are neither pomegranate nor blueberry juice, but rather, apple and grape juice. ... Notwithstanding that Coca Cola's product actually contains little pomegranate or blueberry juice, Coca Cola labels its product as "Pomegranate Blueberry" juice.

JA 26a. In opposing Coca-Cola's motion to dismiss, Pom explained that "Defendant's purported compliance with FDA juice labeling regulations does not preclude Pom's Lanham Act claim. These regulations establish minimum, rather than maximum, standards." Opp. To Mot. To Dismiss at 1, No. 08-06237 (C.D. Cal. Dec. 15, 2008).

2. The district court (Otero, J.) granted Coca-Cola's motion to dismiss in relevant part. At the outset, the court observed that, because "the []FDCA, unlike the Lanham Act, does not provide for a private right of action," it is appropriate to "tread[] carefully when applying the Lanham Act to ... goods ... that are also subject to regulation by the []FDCA." Pet. App. 87a

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[3] In the ingredient statement, *every* ingredient (apart from minor exceptions not relevant here) must be listed "in descending order of predominance by weight." 21 C.F.R. § 101.4(a)(1).

(internal quotation marks omitted; second ellipsis in original). The court dismissed Pom's claim because, *inter alia*, Pom's "claim may be construed to challenge FDA regulations ...." Pet. App. 89a. See also *id.* at 89a-90a ("The []FDCA and the FDA implementing regulations ... involve a number of requirements for labeling a multiple-juice beverage.") (citing 21 U.S.C. §§ 343(f), 343(i)(1); 21 C.F.R. § 102.33).

Portions of Pom's Lanham Act claim that the district court did not dismiss went forward and, on cross-motions for summary judgment, the court adhered to but elaborated on its prior ruling dismissing Pom's challenge to the name and label of Coca-Cola's product. The court addressed for the first time the relative font sizes of the words in the name (an issue that had arisen for the first time on summary judgment), finding that Coca-Cola's label complies with the FDCA in this respect as well. Pet. App. 62a-64a.[4]

3. The court of appeals (D.W. Nelson, O'Scannlain, and N.R. Smith, JJ.) affirmed in a unanimous opinion authored by Judge O'Scannlain. Pet. App. 1a. The

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[4] Pom also asserted state-law claims challenging the name and label. The district court granted summary judgment to Coca-Cola on the ground that Pom lacked "standing" under the relevant California statutes to pursue the claims. Pet. App. 58a-60a. The court of appeals later vacated that part of the judgment based on intervening California Supreme Court precedent. Pet. App. 13a. On remand, the district court again granted summary judgment to Coca-Cola on the state-law claims, this time on the ground that they are preempted by the NLEA. *Pom Wonderful LLC* v. *The Coca-Cola Co.*, No. CV 08-06237, 2013 WL 543361, at *3-*5 (C.D. Cal. Feb. 13, 2013). Pom appealed, and the court of appeals accepted the parties' suggestion to postpone briefing until this Court's decision. No. 13-55770, Dkt. No. 19 (9th Cir. Jan. 31, 2014).

court found that the FDCA precludes Pom's challenge to the name of Coca-Cola's product because "FDA has concluded that a manufacturer may name a beverage using the name of a flavoring juice that is not predominant by volume," so long as the manufacturer "states that those juices are not predominant," as in FDA's example ""Raspcranberry'; raspberry and cranberry flavored juice drink.'" *Id.* at 9a (citing 21 C.F.R. § 102.33(c), (d), and quoting § 102.33(d)(1)). The court found that the name of Coca-Cola's product—insofar as it includes "Pomegranate Blueberry Flavored Blend of 5 Juices ..."—complies with FDA's regulation, and therefore that "Pom's challenge to the name ... would create a conflict with FDA regulations and would require us to undermine the FDA's apparent determination that so naming the product is not misleading." *Ibid.*

Turning to the font sizes on the label, the court described Pom's claim as "focuse[d] on how Coca-Cola presents the words 'Pomegranate Blueberry' and 'Flavored Blend of 5 Juices' on the product's label. ... Pom apparently wants to force Coca-Cola to alter the size of the words on its labeling so that the words 'Pomegranate Blueberry' no longer appear in larger, more conspicuous type on Coca-Cola's label than do the words 'Flavored Blend of 5 Juices.'" Pet. App. 10a. The court found this claim precluded by the FDCA because "allowing Pom to achieve this result would again undermine the ... FDCA and its implementing regulations[, which] have identified the words and statements that must or may be included on labeling

and have specified how prominently and conspicuously those words and statements must appear." *Ibid.*[5]

The court of appeals did not address the merits of Pom's contentions in this Court that Coca-Cola's product is misleading in other respects. The court specifically found that Pom waived its assertion (Br. 2, 52) that, taking into account the percentage make-up of the beverage, the pomegranate and the blueberries depicted in the vignette should have been much smaller relative to the apple and the grapes; the court explained that Pom had not "meaningfully" raised this argument on appeal. Pet. App. 10a.[6] The court did not address, and thus also presumably found waived, Pom's perfunctory assertion (Br. 2, 51) as to Coca-Cola's division of the product's name onto multiple lines.[7] The court did not address Pom's current arguments that Coca-Cola's product's color is mis-leading (Br. 2) or that pomegranate juice and blue-berry juice do not provide the product's flavor (Br. 51), arguments that Pom did not raise in even a perfunctory fashion before the court of appeals.

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[5] Pom (Br. 40) and the United States (Br. 24) ignore these passages of the court of appeals' decision concerning the divergence between Pom's proposed requirements and the FDA regulations in asserting that the court relied on a field preemption/preclusion theory. To the extent the court's decision may be so characterized, Coca-Cola does not rely on that theory in this Court.

[6] Pom made the argument only in a footnote in its opening brief. See Br. for Appellant at 28 n.11, *Pom Wonderful LLC* v. *The Coca-Cola Co.*, 679 F.3d 1170 (9th Cir. 2012) (No. 10-55861). The district court had earlier found that the vignette "clearly complies with FDA requirements relating to the depiction of vignettes." Pet. App. 67a (citing 58 Fed. Reg. 2897, 2918-21 (Jan. 6, 1993)).

[7] See Br. for Appellant, *supra* n.6, at 28 n.11.

4. Given the district court's and court of appeals' threshold ruling that Pom's Lanham Act claim is precluded, those courts did not reach the question whether reasonable jurors could find Coca-Cola's product's name and label misleading. Pom nonetheless discusses (Br. 10-12) that question, omitting any mention of the contrary evidence, which we summarize here.

First, Pom invokes (Br. 10) a survey by its expert, E. Deborah Jay, that found that many potential purchasers of pomegranate and blueberry juice blends are likely to conclude from Coca-Cola's label that its product contains mainly pomegranate and blueberry juices. But Coca-Cola's expert, Ran Kivetz, a professor at Columbia Business School, explained that Ms. Jay's survey suffered from numerous flaws, including use of "highly biased" questions and "an inadequate, commercially unviable, and suspicious control package." JA 173a.

Second, Pom claims that Coca-Cola received a "'record number of complaints'" regarding the product. Pet. Br. 11 (quoting Pet. App. 31a (district court's description of what "Pom contends")). But Pom's assertion distorts the testimony of a Coca-Cola consumer affairs employee, who in fact testified that Coca-Cola had received only a very small number of complaints, most of which had nothing to do with the name or label. See JA 176a ("[l]ess than 1% of the comments, approximately 20 in total, were complaints regarding the Juice's name or labeling").[8]

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[8] There was evidence that Pom itself had directed an employee to "call [Coca-Cola's] customer service numbers and ask what % pomegranate juice is in their blends ... [and] [i]f they won't give her an answer, please have her call back several times ...." Ex.

Third, Pom quotes an internal Coca-Cola email stating that, although "'[w]e are in compliance with the FDA regs related to the naming of juice containing products[,] *[t]here is a risk from a misleading standpoint as the product has less than 0.5% of pomegranate and blueberry juices.*'" Pet. Br. 11-12 (quoting Pet. App. 34a-35a) (emphasis Pom's). But the "risk" to which the e-mail referred was the risk of an unmeritorious lawsuit, not the risk that consumers would actually be misled by a juice name and label that comply fully with FDA's detailed regulations on these subjects. See Deft. Reply St. To Pltf. St. Of Genuine Issues at 27, No. 08-06237, Dkt. No. 239 (C.D. Cal. Jan. 15, 2010). In any event, the email was not written by a lawyer and did not purport to address the legal issues resolved by the courts below in Coca-Cola's favor.

SUMMARY OF ARGUMENT

I

Interpreting a later, more specific law to narrow the scope of an earlier, more general law is a "classic judicial task," *United States* v. *Fausto*, 484 U.S. 439, 453 (1988), not an implied repeal. In such circumstances, this Court has rejected the implied-repeal framework and instead has sought to reconcile the two federal laws based on the usual statutory-interpretation indicia of "text, structure, and purpose," *Elgin*, 132 S. Ct. at 2133. This approach recognizes that it is unrealistic to expect that Congress, in enacting one federal law, is aware of and should address every possible impact of that enactment on older federal laws.

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18 To Decl. Of S. Zalesin ISO Mot. In Limine, No. 08-06237, Dkt. No. 198 (C.D. Cal. Feb. 2, 2010).

This framework applies here. The Lanham Act was enacted in 1946 and applies to "goods and services" of all types. The NLEA was enacted in 1990 and seeks "national uniform[ity]" on certain aspects of food naming and labeling. The question thus is not whether the NLEA impliedly repeals Lanham Act § 43(a), but whether the NLEA narrows the scope of that Lanham Act section in the circumstances here.

II

The answer is yes. The text, structure, and purpose of the NLEA (and FDCA) demonstrate, *first*, an overriding congressional intent to achieve national uniformity in food/juice naming and labeling and to bar private lawsuits that undermine that goal; and *second*, a comprehensive federal regulatory scheme in the FDCA (and regulations thereunder) that is far more specific than Lanham Act § 43(a) as to food/juice naming and labeling.

Where one federal law discloses Congress's intent to achieve national uniformity, this Court has readily inferred Congress's intent to narrow the scope of (or bar altogether) a private cause of action under a second federal law that would undermine Congress's uniformity goal. The courts of appeals have consistently followed that approach where Congress's uniformity goal is revealed by a provision that expressly preempts state-law suits but is silent as to narrowing or preclusion of private federal-law suits.

Here, even before the NLEA's enactment, Congress's intent that there be national uniformity in food and juice naming and labeling was evident from 21 U.S.C. § 337(a), the FDCA's provision barring private enforcement of the FDCA's provisions. The NLEA confirmed and further implemented the national-

uniformity goal. Its "National Uniform Nutrition Labeling" provision expressly preempts state requirements that are "not identical" to the requirements in certain FDCA provisions. Congress's evident purpose was to allow food and juice manufacturers to comply with a single standard nationwide. Private state-law suits would disrupt that national uniformity by exposing manufacturers to an array of different standards proposed by the plaintiffs.

Accordingly, it is appropriate to infer that Congress intended to preclude a Lanham Act § 43(a) suit that poses the same threat to national uniformity as that posed by a state-law suit within the express terms of the preemption clause. Petitioner's claims, if pleaded as a state-law suit, would be squarely within the preemption clause. Each of petitioner's assertions is covered by an FDCA requirement that is given preemptive force by the NLEA, and petitioner has conceded that its proposed requirements seek to heighten (and thus are "not identical to") the requirements prescribed by the FDCA.

The specificity of the food/juice naming and labeling provisions of the FDCA/NLEA (and FDA's regulations thereunder) relative to the broad and general language of Lanham Act § 43(a) further shows that Congress intended to preclude a Lanham Act claim in the circumstances here. FDA's regulations authorize the name and label of respondent's product in every respect challenged by petitioner. For example, the name "POMEGRANATE BLUEBERRY FLAVORED BLEND OF 5 JUICES" is authorized by 21 C.F.R. § 102.33(b)-(d). And because "FLAVORED BLEND OF 5 JUICES" is more than one-half the height of "POMEGRANATE BLUEBERRY," the font size

satisfies the cross-referenced requirement, *id.* § 101.22(i)(1)(iii), that these words be "not less than one-half the height of the letters used in the name of the characterizing flavor," as well as the more general requirement that the name "shall be in a size reasonably related to the most prominent printed matter," *id.* § 101.3(d).

The existence of some manufacturer discretion (within the bounds of these requirements) to choose its own nationally-uniform label does not indicate Congress's or FDA's intent to allow private plaintiffs to invoke Lanham Act § 43(a), under the guise of more stringent enforcement, to urge a host of different requirements on food manufacturers. To the contrary, as Congress and FDA recognized, such a regime would undermine Congress's overriding goal of national uniformity.

III

Petitioner's remaining arguments are unpersuasive. *First*, the suggestion that FDA lacks adequate resources to regulate food labels for potential to mislead is belied by FDA's certification that the relevant FDCA provisions were "adequately implemented," and in any event the answer to any asserted resources problem is not to allow private Lanham Act lawsuits at the expense of national uniformity. *Second*, petitioner overstates the extent to which Lanham Act § 43(a) would be curtailed in other sectors by a holding that the claims in this case are precluded by the FDCA and NLEA. Petitioner's examples involve neither the express preemption clause nor the detailed set of regulations at issue here. The judgment of the court of appeals should be affirmed.

ARGUMENT

I. A SPECIFIC FEDERAL LAW CAN NARROW THE SCOPE OF A GENERAL FEDERAL LAW EVEN IF IT DOES NOT EXPRESSLY SO INDICATE AND EVEN IF THE TWO LAWS ARE NOT IN IRRECONCILABLE CONFLICT

As the United States agrees (Br. 11-12, 16-18), petitioner is incorrect to invoke (Br. 20-21) the canon against implied repeal as barring FDCA/NLEA's preclusion of its Lanham Act claim. This Court has repeatedly held that the implied-repeal canon does not apply where, as here, a later, more specific law clarifies or narrows the otherwise broad scope of an earlier law.[9] And contrary to petitioner's suggestion (Br. 19-20), this Court has never put Congress to the burden of *explicitly* addressing the impact of one law on every other corner of the U.S. Code.

In *Fausto*, for example, this Court considered whether the Civil Service Reform Act's ("CSRA") "elaborate 'new framework for evaluating adverse personnel actions against [federal employees],'" 484 U.S. at 443 (quoting *Lindahl* v. *OPM*, 470 U.S. 768, 774 (1985)) (bracket in original), precluded a federal employee "from seeking the Claims Court review

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[9] A specific law may narrow the scope of a general law even if the general law comes later in time. *See, e.g.*, *Morton* v. *Mancari*, 417 U.S. 535, 550-51 (1974) ("Where there is no clear intention otherwise, a specific statute will not be controlled or nullified by a general one, *regardless of the priority of enactment*.") (emphasis added). For example, in *Morton*, 417 U.S. at 550-51, the Court found the general anti-discrimination provision of Title VII narrowed by an exception (based on the Indian Reorganization Act) allowing the Bureau of Indian Affairs to grant preferences to Indians in the Bureau's hiring and promotion process.

traditionally available under the [earlier-enacted] Tucker Act ... [and] Back Pay Act," *id.* The CSRA did not explicitly address its impact upon those earlier statutes. See *id.* at 456 (Stevens, J., dissenting). This Court nonetheless asked whether Congress's intent to effect such preclusion through the CSRA was "fairly discernible," and found that it was. *Id.* at 452 (majority opinion). The Court deemed inapposite "the doctrine that repeals by implication are strongly disfavored," *ibid.*, explaining:

> Repeal by implication of an express statutory text is one thing; it can be strongly presumed that Congress will specifically address language on the statute books that it wishes to change. But repeal by implication of a legal disposition implied by a statutory text is something else. The courts frequently find Congress to have done this—whenever, in fact, they interpret a statutory text in the light of surrounding texts that happen to have been subsequently enacted. This classic judicial task of reconciling many laws enacted over time, and getting them to 'make sense' in combination, necessarily assumes that the implications of a statute may be altered by the implications of a later statute.

Id. at 453 (internal citation omitted). See also, *e.g.*, *Elgin*, 132 S. Ct. at 2133 (holding, without reference to implied repeal, that CSRA impliedly narrows the ability of certain litigants to sue in federal district court under 28 U.S.C. § 1331); *United States* v. *Estate of Romani*, 523 U.S. 517, 530 (1998) ("Given the fact that this basic question of interpretation [of a 1797 statute] remains unresolved, it does not seem appropriate to view the issue in this case as whether the Tax

Lien Act of 1966 implicitly amended or repealed the [1797] statute. Instead, we think the proper inquiry is how best to harmonize the impact of the two statutes ...."); *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 143 (2000) ("At the time a statute is enacted, it may have a range of plausible meanings. Over time, however, subsequent acts can shape or focus those meanings. ... This is particularly so where the scope of the earlier statute is broad but the subsequent statutes more specifically address the topic at hand.") (internal citation omitted); *Bhd. of R.R. Trainmen* v. *Chicago River & Ind. R. R. Co.*, 353 U.S. 30, 42 (1957) ("the specific provisions of the Railway Labor Act take precedence over the more general provisions of the Norris-LaGuardia Act").

Indeed, this Court has taken such an approach to Lanham Act § 43(a), the general statutory provision at issue here, in *Dastar Corp.* v. *Twentieth Century Fox Film Corp.*, 539 U.S. 23 (2003). *Dastar* involved the scope of that section's cause of action against a defendant who makes "a 'false designation of origin.'" *Id.* at 31 (quoting 15 U.S.C. § 1125(a)). This Court observed that "'origin'" could conceivably "include not merely the producer of the physical item ... but also the creator of the content that the physical item conveys." *Id.* at 33. But this Court, without discussing implied repeal, found Congress's subsequent enactment of copyright statutes (which did not expressly mention the Lanham Act) to narrow that otherwise broad scope. *Id.* at 33-34. Those copyright statutes addressed the matter more "specifically," *id.* at 33, than did Lanham Act § 43(a).[10]

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[10] As *Dastar* demonstrates, one federal law can narrow specific words in another federal law. See also *Fausto*, 484 U.S. at 454 (CSRA narrowed scope of the words "appropriate authority" in

This case presents a similar scenario: Years after enacting the broad and general provisions of the 1946 Lanham Act, Congress enacted the 1990 NLEA recognizing that certain specific FDCA provisions governing food naming and labeling should be "national[ly] uniform." NLEA § 6. The implied-repeal framework does not apply, and the proper inquiry instead is "how best to harmonize the impact of the two statutes," *Estate of Romani*, 523 U.S. at 530, in keeping with "Congress' intent," *id.* at 533. As explained in Point II, *infra*, Congress intended to preclude a Lanham Act § 43(a) claim in the circumstances here.[11]

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the Back Pay Act to no longer include the Court of Claims); *Keogh* v. *Chicago & N.W. Ry. Co.*, 260 U.S. 156, 163 (1922) (Brandeis, J.) (once Interstate Commerce Commission fixed carriers' rates, shippers could not complain that the rates constituted "violation of ... [their] legal rights," and hence could not assert that they had been "'injured in [their] business or property'" as required to bring a cause of action under the Anti-Trust Act) (quoting Anti-Trust Act of July 2, 1890, c. 647, 26 Stat. 209). Similarly here, for the reasons discussed in Point II, *infra*, the NLEA and FDCA narrow the words "false or misleading" in Lanham Act § 43(a) so that they do not reach aspects of a nationally-uniform juice label that have been chosen in compliance with the FDCA and FDA's regulations. Accord, U.S. Br. 18.

[11] Even if the implied-repeal framework did apply (which it does not), petitioner overstates (Br. 21) its requirements. By definition, an *implied* repeal does not require an express statement in the later law, even when an earlier Congress purported to require one. See *Lockhart* v. *United States*, 546 U.S. 142, 148 (2005) (Scalia, J., concurring). Moreover, the implied-repeal framework does not require that it is impossible to comply with both laws. See *Credit Suisse Secs. (USA) LLC* v. *Billing*, 551 U.S. 264, 273 (2007) (a conflict may be found where one statute "forbid[s] the very thing that the [other statute] ... *permit[s]*") (emphasis added). Accordingly, it is irrelevant that "neither the

II. THE FDCA AND NLEA NARROW THE SCOPE OF LANHAM ACT § 43(A) IN THE CIRCUMSTANCES HERE

Under the appropriate analytic framework, which involves "reconciling ... laws enacted over time, and getting them to 'make sense' in combination," *Fausto*, 484 U.S. at 453, the FDCA and NLEA preclude petitioner's proposed Lanham Act § 43(a) claim against respondent's juice-blend name and label. The touchstone is "Congress' intent," *Estate of Romani*, 523 U.S. at 533, as revealed by the relevant statutes' "text, structure, and purpose," *Elgin*, 132 S. Ct. at 2133.

The text, structure, and purpose of the FDCA and NLEA demonstrate Congress's clear intent to achieve national uniformity in food and juice naming and labeling that would be defeated by Lanham Act claims like petitioner's. The relevant textual provisions here include, *first*, the FDCA's delegation of authority to enforce its provisions exclusively to the federal government (and in certain limited instances the States), rather than private parties, 21 U.S.C. § 337; *second*, the NLEA's "national uniform[ity]" provision, which expressly preempts private state-law actions that seek to impose requirements "not identical" to enumerated FDCA provisions, NLEA § 6; and *third*, the FDCA's

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FDCA's statutory provisions on food labeling nor FDA's implementing regulations *require* Coca-Cola" (Pet. Br. 22) (emphasis added) to use a name or label that petitioner contends is misleading. Although *Department of Transportation* v. *Public Citizen*, 541 U.S. 752 (2004) (cited at Pet. Br. 24), observed that the "irreconcilable conflict" standard would be satisfied where the regulated entity cannot comply with both statutes, *id.* at 766-67, the Court did not address or decide whether the standard could be satisfied in the *Credit Suisse* scenario where one statute forbids, and a second statute permits, certain conduct.

substantive provisions (and FDA regulations thereunder), which are substantially more specific than is Lanham Act § 43(a) as to food and juice naming and labeling. These provisions together reveal a comprehensive regulatory structure whose purpose is to make food and juice naming and labeling nationally uniform, relieving manufacturers of the difficulties of complying with an array of divergent standards proposed by private plaintiffs. The legislative history of the NLEA confirms this overriding national-uniformity goal.

A. The FDCA Delegates Enforcement Authority To The Federal Government Rather Than To Private Plaintiffs

Even before the NLEA's enactment, Congress's desire for national uniformity was apparent from the FDCA's delegation of enforcement authority exclusively to the federal government rather than to private plaintiffs (subject to certain limited enforcement rights for the States). See 21 U.S.C. § 337(a) ("[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."); *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001) (§ 337 is "clear evidence" that the FDCA is to "be enforced exclusively by the Federal Government"). Cf. *Astra USA, Inc.* v. *Santa Clara Cnty.*, 131 S. Ct. 1342, 1347, 1349 (2011) ("Congress vested authority to oversee compliance with the 340B Program in HHS and assigned no auxiliary enforcement role to covered entities," and thus enabled HHS "to administer both Medicaid and § 340B harmoniously and on a uniform, nationwide basis").

B. The NLEA Further Implemented The National-Uniformity Goal Through An Express Preemption Clause

The NLEA confirmed and further implemented Congress's national-uniformity goal. Specifically, NLEA § 6, entitled "National Uniform Nutrition Labeling," preempts, *inter alia*, any state-law "requirement for the labeling of food of the type required by section ... 403(f) [regarding conspicuousness] ... [and] 403(i)(1) [regarding common or usual name] ... that is not identical to the requirement of such section." NLEA § 6(a)(3) (codified in part at 21 U.S.C. § 343-1(a)(3)). This provision supports a strong inference that Congress intended to preclude private suits under Lanham Act § 43(a) that pose the same threat to national uniformity as do private state-law suits.

In *Fausto*, *Elgin*, and other decisions, this Court has inferred a congressional intent to achieve national uniformity from the comprehensive structure of the federal law at issue, and has then held that this national-uniformity goal requires narrowing the scope of an earlier-enacted law. In *Fausto*, for example, this Court observed that "[a] leading purpose of the CSRA was to replace the haphazard arrangements for administrative and judicial review of personnel action," 484 U.S. at 444, with a scheme of Merit Systems Protection Board ("MSPB") "administrative review ... followed by judicial review in the Federal Circuit," *id.* at 447. *Fausto* held that the CSRA impliedly precluded certain suits under the Tucker Act and Back Pay Act because such suits would undermine national uniformity. *Id.* at 451 (instead of being directed to the MSPB and in turn the Federal Circuit, certain "employees would be able to obtain review in the district courts and the regional courts of appeals

throughout the country, undermining the consistency of interpretation by the Federal Circuit"). See also *Elgin*, 132 S. Ct. at 2135 (similar); *Keogh* v. *Chicago & N.W. Ry. Co.*, 260 U.S. 156, 163 (1922) (Brandeis, J.) (law entrusting to a federal agency the task of approving carriers' rates required preclusion of private antitrust suits because, if such suits were allowed, "[u]niform treatment would not result ... unless the highly improbable happened, and the several juries and courts gave to each the same measure of relief").

The courts of appeals have applied that principle in the specific context of a provision, like the NLEA's, that expressly preempts state law and is silent on preclusion of an earlier-enacted federal law. These courts have consistently inferred from such a provision that Congress intended to preclude private suits under the "other" federal law because they would pose the same threat to national uniformity as would the expressly-preempted private suits under state law. See *Lane* v. *R.A. Sims, Jr., Inc.*, 241 F.3d 439, 443 (5th Cir. 2001) (inferring from Federal Railroad Safety Act's ("FRSA") provision expressly preempting state-law negligence claims that Congress also intended to preclude Federal Employers' Liability Act ("FELA")-based negligence claims). As the court of appeals explained in *Lane*:

> [U]niformity can be achieved only if the regulations ... are applied similarly to a FELA plaintiff's negligence claim and a ... state law negligence claim. ... [A]llowing juries in FELA cases to find negligence ... even though [the railroad complied with] the FRSA regulations, would further undermine uniformity, because it would result in the

> establishment, through such verdicts, of varying, uncertain [requirements].

Id. at 443-44. Accord, *Waymire* v. *Norfolk & W. Ry. Co.*, 218 F.3d 773, 777 (7th Cir. 2000); *Nickels* v. *Grand Trunk W. R.R., Inc.*, 560 F.3d 426, 430 (6th Cir. 2009).[12]

Similarly here, there is a strong basis to infer that Congress intended to preclude federal Lanham Act suits at least to the same extent that it intended to preempt state-law suits that fall within the express preemption clause. The legislative history confirms the inference, as NLEA's sponsors elaborated on why national uniformity was needed in this area. For example, Senator Hatch explained:

> [I]nconsistent State and local laws seriously disrupt food manufacturing and distribution, resulting in higher prices for consumers. Moreover, they frustrate food safety and nutrition education efforts by presenting

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[12] *Lane* also noted that, absent preclusion of FELA suits, there would be an inequality between railroad employees (who could sue under FELA) and others (who lack standing under FELA and who are expressly preempted from suing under state law). 241 F.3d at 443. Petitioner's proposed regime would create a similar inequality by allowing business entities to sue under the Lanham Act while depriving consumers of any corresponding ability to sue (because they lack standing under the Lanham Act and are expressly preempted by the NLEA from suing under state law).

Courts of appeals that have declined to find FELA claims precluded, see *Cowden* v. *BNSF Ry. Co.*, 690 F.3d 884, 893-94 (8th Cir. 2012); *Tufariello* v. *Long Island R.R. Co.*, 458 F.3d 80, 86 (2d Cir. 2006), reasoned that the FRSA regulations at issue in those cases (unlike those at issue in the cases cited in text) did not address the circumstances underlying the FELA claim.

> consumers with varying and inconsistent information and warnings.

136 Cong. Rec. S16607, 16611 (Oct. 24, 1990). See also, *e.g.*, 136 Cong. Rec. H5836, 5840 (July 30, 1990) (statement of Rep. Waxman) ("A national food processor understandably finds it difficult to comply with numerous conflicting and inconsistent State and local laws."); *id.* at 5843 (statement of Rep. Madigan) (similar);[13] 58 Fed. Reg. at 2462 ("[I]n enacting the 1990 amendments, Congress decided that even though Federal requirements may preempt more restrictive State requirements in certain instances, the net benefits from national uniformity in these aspects of the food label outweigh the loss in consumer protection that may occur as a result.") (citing statement of Rep. Madigan).[14]

Petitioner's proposed requirements would be within the express terms of the NLEA's preemption clause if asserted in a state-law suit.[15] *First*, petitioner has conceded that it seeks to enforce Lanham Act requirements above any "floor" set by the FDCA, and thus that its proposed requirements are necessarily "not identical" to those imposed by the FDCA. See,

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[13] There was no Senate Report on the NLEA, and the House Report, H.R. Rep. No. 101-538 (June 13, 1990), preceded the July 30, 1990, addition to the bill of preemption as to the FDCA provisions at issue here.

[14] From the standpoint of consumer deception as well, it would make little sense to preempt consumers from suing under state law, but to allow business entities to sue under the Lanham Act on a theory that deception caused the consumers to buy from the defendant rather than the plaintiff.

[15] The district court below indeed held that petitioner's state-law claims challenging the name and label of respondent's product are preempted. See *supra*, n.4.

e.g., Opp. To Mot. To Dismiss First Amended Compl. at 10, No. 08-06237 (C.D. Cal. Aug. 26, 2009) ("Pom's claim is based on the fact that the product's naming and labeling is misleading even if they comply with the minimum requirements set forth by the FDA regulations."); Pet. Br. 32 ("FDA's regulations bespeak an intent to set a floor—but not a ceiling—on the adequacy of labeling."). That concession is appropriate, for as shown in detail in Point II.C, *infra*, each of petitioner's proposed requirements diverges from the relevant provisions of the FDCA and FDA's regulations thereunder.

Second, petitioner's claims are covered by FDCA provisions enumerated in the NLEA's preemption clause. Specifically, petitioner contends in this Court that respondent's product is misleading with regard to (1) name (Br. 22-23, 49-52); (2) font size (Br. 23, 47); (3) vignette (Br. 52); (4) division of the name onto multiple lines (Br. 10, 51); and (5) coloring (Br. 2).[16] But the name and the vignette are covered by FDCA § 403(i)(1), which addresses "the common or usual name" of a juice. 21 U.S.C. § 343(i)(1).[17] Petitioner's assertions concerning the height of the words on the label and the division of the product's name onto multiple lines are addressed by FDCA § 403(f), which requires that words be placed on the label "with such conspicuousness (as compared with other words ...) ... as to render [them] likely to be read and understood by the ordinary individual under customary conditions

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[16] As explained *infra*, at 45-47, petitioner's arguments as to the vignette, the division of the name onto multiple lines, and the color are waived.

[17] FDA has treated vignettes under FDCA § 403(i)(1) on the theory that a vignette bears on the product's name. See 56 Fed. Reg. at 30462.

of purchase and use." 21 U.S.C. § 343(f). And any issue of supposedly misleading purple coloration is covered by FDCA § 403(i)(2), which provides in relevant part that "colors not required to be certified under section 379e(c) of this title unless sold as ... such colors[] may be designated as ... colorings without naming each." 21 U.S.C. § 343(i)(2) (footnote omitted).

These FDCA provisions allow the manufacturer to employ a single name and label nationwide—rather than be subjected to "a multitude of dispersed and uncoordinated lawsuits," *Astra*, 131 S. Ct. at 1349, proposing a range of different requirements. For example, as to relative conspicuousness of the words on the label, one plaintiff might insist that "FLAVORED BLEND OF 5 JUICES" be three-quarters the height of "POMEGRANATE" and "BLUEBERRY"; another might insist on equal height; another might insist on equal height and bold font; and so on. See also *supra*, at 2. "Uniform treatment would not result ... unless the highly improbable happened, and the several juries and courts gave to each [plaintiff] the same measure of relief." *Keogh*, 260 U.S. at 163. That is the antithesis of what Congress intended when it enacted a "national uniform[ity]" provision to solve the problem that, as one sponsor put it, "[a] national food processor understandably finds it difficult to comply with numerous conflicting and inconsistent State and local laws," 136 Cong. Rec. at 5840 (statement of Rep. Waxman).

The NLEA's preemption clause undermines petitioner's reliance (Br. 32-34) on *Wyeth* v. *Levine*. In that case, in finding that the FDCA did not preempt a state-law claim, this Court emphasized that Congress had *not* "enacted an express pre-emption provision" for

prescription drugs. 555 U.S. at 574. Here, with the goal of providing a nationally-uniform standard for the food industry, Congress *did* enact an express preemption clause for certain food naming and labeling issues. Under *Fausto* and other cases discussed above, it is appropriate to infer from such textual and structural evidence Congress's intent to preclude private suits brought under the generally-worded Lanham Act § 43(a) if (as here) they would be expressly preempted if brought as state-law claims.[18]

Petitioner's and the United States' attempts to escape the NLEA's preemption clause and the inference it supports are unpersuasive. They ignore the purpose of the clause and the fact that petitioner seeks to do through the Lanham Act what it could not do through a state-law claim—namely, enforce requirements for blended fruit-juice naming and labeling that are "not identical" to the relevant FDCA provisions (or its implementing regulations).

Petitioner's Arguments. *First*, petitioner speculates that Congress considered but declined to enact a clause expressly precluding private suits under non-FDCA federal statutes. See Br. 29 n.5 (noting legislative history's description of NLEA's preemption

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[18] The NLEA's preemption clause, in exempting safety requirements, see § 6(c)(2), highlights another reason why *Wyeth* v. *Levine* is inapposite. Whereas *Wyeth* involved a tragic side-effect from a drug that required amputation of the plaintiff's forearm, 555 U.S. at 559, this case involves no such safety issue, but rather an allegation that FDA's regulations are inadequate to prevent consumers from being misled and thus have harmed petitioner. *Wyeth*'s calculus that the uniformity benefit of preemption did not outweigh the cost there (eliminating a source of redress for a physically-injured plaintiff) hardly supports the same conclusion here.

clause as "carefully crafted," "limited in scope," and a "compromise") (internal quotation marks omitted). But these references do not show that Congress considered private suits under non-FDCA federal statutes, or whether to preclude such suits.[19] Rather, they pertain to Congress's decision to limit the express preemption clause to the FDCA provisions referenced therein (which, as discussed above, cover petitioner's assertions), and to provide explicitly that courts should not use implied-preemption analysis to go beyond the scope of that clause. See NLEA § 6(c)(1) ("The [NLEA] shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under section 403A of the [FDCA] [which was added by NLEA § 6(a)]."). That Congress prohibited courts from holding impliedly preempted state-law suits that fall *outside* the scope of the express preemption clause does not suggest that Congress prohibited courts from inferring that Congress intended to preclude suits under the Lanham Act that would fall *within* the express preemption clause if asserted under state law.

Second, petitioner asserts (Br. 29) that "Congress was well aware that the Lanham Act applied to misleading food labels when it decided to displace only state-law labeling requirements." But petitioner offers scant support, principally citing (*ibid.*) two lower-court decisions over the 44-year period between 1946 (the Lanham Act) and 1990 (the NLEA). See Pet. Br. 29 (citing *Hesmer Foods, Inc.* v. *Campbell Soup Co.*, 346 F.2d 356, 359 (7th Cir. 1965); *Potato Chip Inst.* v. *General Mills, Inc.*, 333 F. Supp. 173 (D.

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[19] As shown in Point I, *supra*, the lack of an *express* preclusion of other federal laws is not dispositive. This Court routinely finds *implied* preclusion based on indicia of Congress's intent.

Neb. 1971), aff'd, 461 F.2d 1088 (8th Cir. 1972) (per curiam)).[20] Compare *Wyeth*, 555 U.S. at 575 (Congress was aware of "*prevalen[t]* ... state tort litigation") (emphasis added). Petitioner's reliance (Br. 30) on two snippets of legislative history that made passing reference to the Lanham Act[21] is equally unavailing.

Third, while appearing to concede (Br. 31) that its claims are regulated by FDCA subsections 403(i)(1), (i)(2), and (f) (each of which has preemptive force under the NLEA's preemption clause), petitioner argues that its claim is akin to a claim under subsection 403(a) (which does not). But Congress cannot have contemplated that the preemption clause could be nullified simply because a plaintiff invokes subsection 403(a) rather than one or more of the subsections that have preemptive effect under the NLEA's preemption clause. Subsection 403(a), an obviously general provision, instead covers circumstances that are *not* covered by one or more of the subsections that have preemptive effect. See, *e.g.*, 56 Fed. Reg. 60528, 60530 (Nov. 27, 1991) ("State requirements that would not be subject to the preemption provisions of the 1990 amendments ... includ[e] *State laws pertaining to issues for which there is no*

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[20] Notably, unlike here, see Point II.C, *infra*, neither case involved an FDA regulation addressing the challenged labeling aspect, *i.e.*, "the word 'barbecue' in the name Campbell's Barbecue Beans," *Hesmer Foods*, 346 F.2d at 359, and the "use of 'potato chip' for a product of dehydrated potatoes," *Potato Chip Inst.*, 333 F. Supp. at 180 (discussing non-binding FDA policy guideline).

[21] See *Health & Nutrition Claims in Food Advertising & Labeling, Hearing Before the S. Comm. on Gov't Affairs*, 101st Cong. 74 (1990); *FDA's Continuing Failure to Regulate Health Claims for Foods, Hearings Before the Subcomm. on Human Res. & Intergov'tl Relations of the H. Comm. on Gov't Operations*, 101st Cong. 157 (1989).

national framework, such as open date labeling, unit price labeling, container deposit labeling, religious dietary labeling, and previously frozen labeling") (emphasis added); 58 Fed. Reg. 2478, 2484 (Jan. 6, 1993) (labeling issue "outside the coverage of section 403(r)(1)(B) ... would be subject to section 403(a)").[22] So understood, the NLEA's preemption clause works as intended. Private plaintiffs are prohibited from disrupting the FDCA's nationally-uniform standard where a specific standard exists—*i.e.*, in situations covered by one or more of the § 403 subsections that have preemptive effect. But private plaintiffs can bring suit under state law or the Lanham Act where no such specific FDCA standard exists—*i.e.*, in the situation covered by subsection 403(a).[23]

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[22] Although FDA has occasionally used subsection (a) as a shorthand for other subsections, see, *e.g.*, Warning Letter from FDA to Brad Alford, dated December 4, 2009, *available at* http://www.fda.gov/iceci/enforcementactions/warningletters/ucm194122.htm (cited at Pet. Br. 37 n.6), those documents were more informal than the rulemaking statements (cited in text) in which FDA focused on the issue.

[23] As noted *supra*, at 27, petitioner has described its suit as seeking to go above the FDCA provisions that have preemptive effect. Any attempt by petitioner to enforce those provisions would be barred by 21 U.S.C. § 337(a). See II.A, *supra*. And § 337(a) cannot be avoided by the end run of purporting to enforce an identical state-law or Lanham Act equivalent of one of the covered FDCA provisions. Cf. *Astra*, 131 S. Ct. at 1348 (in context of analogous statutory scheme, rejecting a plaintiff's attempted end run around the lack of a private cause of action). The NLEA's preemption clause, whose goal was "national uniform[ity]," cannot sensibly be construed to have endorsed such an end run by preempting only "not identical" state requirements (without addressing "identical" ones). Instead, Congress assumed that "identical" requirements were already, and would remain, impliedly preempted by § 337(a). Precedent is not to the contrary. Although *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), and *Riegel*

The United States' arguments. The United States acknowledges (Br. 20) that the NLEA's preemption clause distinguishes this case from *Wyeth* v. *Levine*, but then declines (Br. 25) to infer from that clause that Congress intended to preclude all private suits under the Lanham Act that would fall within the express terms of the preemption clause if they were state-law suits. The United States' reasons for refusing to draw that inference, set forth in a brief rather than a regulation or rulemaking statement, do not warrant deference. See, *e.g.*, *Republic of Austria* v. *Altmann*, 541 U.S. 677, 701 (2004) (United States' views in an *amicus* brief on "a 'pure question of statutory construction' ... merit no special deference") (quoting *INS* v. *Cardoza-Fonseca*, 480 U.S. 421, 446 (1987)). Moreover, they are unpersuasive:

First, the United States argues (Br. 25) that the preemption clause, because not completely exhaustive, proves that Congress was not interested in national uniformity after all. Specifically, the United States notes that the NLEA's preemption clause does not apply to "*all* misbranding provisions" (*ibid.* (emphasis added) (citing 21 U.S.C. § 343(a)(1))),[24] and allows States to obtain exemptions as to non-identical state-law requirements that otherwise would be preempted

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v. *Medtronic, Inc.*, 552 U.S. 312 (2008), involved the FDCA, neither addressed § 337(a). The federal law at issue in *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431 (2005), did not contain any equivalent to § 337(a).

[24] The United States does not endorse petitioner's argument that its suit can be characterized as akin to a suit to enforce FDCA § 403(a), and hence outside the scope of the NLEA's preemption clause. The United States thus appears to agree that Lanham Act claims like petitioner's, if asserted under state law, would come within that clause's scope.

by the preemption clause (*ibid.* (citing 21 U.S.C. § 343-1(b))). But the United States does not contend that either of those carve-outs applies here,[25] and it provides no explanation why the existence of the carve-outs means that Congress abandoned its national-uniformity goal in circumstances (like those here) that *are* within the preemption clause's scope.

Second, the United States mischaracterizes respondent as seeking a "total displacement of a federal remedy" (Br. 25), which the United States views (*ibid.*) as inconsistent with Congress's partial limitation of state remedies through the preemption clause. In fact, respondent seeks the *same* preclusion of federal Lanham Act claims as there would be preemption of analogous state-law suits under the NLEA's preemption clause. Again, the United States does not contest that petitioner's claims here would be squarely within the preemption clause if asserted as state-law claims.

Finally, the United States argues (Br. 25-26 n.10) that the NLEA preemption clause's explicit mention of state-law suits and not federal-law suits suggests that Congress did not view the latter as undermining national uniformity. But cases like *Fausto*, *Elgin*, *Keogh*, *Lane*, *Waymire*, and *Nickels*—none of which the United States addresses—demonstrate that Congress's silence on precluding federal-law suits is not dispositive where other textual or structural indicia reveal Congress's intent to preclude such suits.

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[25] The United States further observes (Br. 25 (citing 21 U.S.C. § 337(b))) that States may enforce FDCA's provisions under certain circumstances. But only States, not private parties, can avail themselves of this provision, and then only after allowing FDA to pursue enforcement first. This provision thus is more consistent with national uniformity than opposed to it.

And in this context, unlike in the preemption context where considerations of federalism are at stake, there is no presumption against preclusion. Compare, *e.g.*, *Elgin*, 132 S. Ct. at 2133 ("we examine the [federal law's] text, structure, and purpose"), with *Altria Group, Inc.* v. *Good*, 555 U.S. 70, 77 (2008) ("When addressing questions of express or implied pre-emption, we begin our analysis 'with the assumption that the historic police powers of the States [are] not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress.'") (bracket in original) (quoting *Rice* v. *Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)). Accord, Brief Of Alaska *et al.* As *Amici Curiae* In Support Of Petitioner ("Alaska Br.") 3, 5. The remainder of the United States' argument (Br. 25-26 n.10) simply relies on petitioner's argument (Br. 29-31) and is unpersuasive for the reasons set forth *supra*, at 30-33.

C. Congress Regulated Food And Juice Naming And Labeling With Far More Specificity In The FDCA And NLEA Than In Lanham Act § 43(a)

As discussed in Point I, *supra*, a key consideration in determining whether one federal law narrows the scope of another federal law is whether the former is more specific than the latter regarding the subject at hand. See, *e.g.*, *Dastar*, 539 U.S. at 34; *Fausto*, 484 U.S. at 454. The FDCA provisions discussed above are plainly more specific regarding juice naming and labeling than is Lanham Act § 43(a), which speaks broadly to goods and services of any type. The FDA's regulations implementing the FDCA provisions are yet more specific. This specificity provides an additional ground for finding petitioner's Lanham Act claim precluded here.

Those regulations should be understood against the backdrop of FDA's certification, pursuant to the NLEA, that FDA's regulations "adequately implement" the FDCA subsections covered by the preemption clause. Congress postponed the effectiveness of the preemption clause until FDA determined that FDCA subsections 403(i)(1) and 403(f) were "adequately implemented." NLEA § 6(b)(3)(B).[26] FDA subsequently made that determination. See 58 Fed. Reg. at 2473 ("FDA finds that [its regulatory] requirements adequately implement section 403(f) of the act."); *id.* at 2474 ("FDA concludes that it does have a strong and adequate regulatory system in place to implement section 403(i)(1) of the act."). Thus, this is not, as in *Wyeth*, a circumstance where "FDA ha[d] paid very little attention to the issues raised," *Wyeth*, 555 U.S. at 581 n.14 (internal quotation marks omitted), and petitioner and the United States are incorrect to ignore FDA's certification of adequate implementation in arguing that FDA has not yet given adequate attention to certain aspects of juice naming and labeling.

As shown below, the regulations specifically authorize each aspect of the name and label of respondent's product. Petitioner's and the United States' arguments to the contrary are unpersuasive. Nor does the United States' interpretation of the regulations deserve deference here, for it ignores, *inter alia*, FDA's recognition of Congress's national-uniformity goal, 58 Fed. Reg. at 2462, and departs from FDA's formal

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[26] The portion of the preemption clause giving preemptive force to FDCA § 403(i)(2) went into effect immediately. See NLEA § 6(a) (making only FDCA § 403A(a)(3) (which covers, *inter alia*, § 403(f) and (i)(1)), not § 403A(a)(2) (which covers, *inter alia*, § 403(i)(2)), subject to the postponement measure in NLEA § 6(b)).

declaration that FDCA § 403(f) and (i)(1) were adequately implemented. See *PLIVA, Inc.* v. *Mensing*, 131 S. Ct. 2567, 2575 (2011) (FDA's interpretation of its regulations in a brief filed by the United States is "'controlling unless plainly erroneous or inconsistent with the regulation[s]' or there is any other reason to doubt that they reflect the FDA's fair and considered judgment") (quoting *Auer* v. *Robbins*, 519 U.S. 452, 461 (1997)) (bracket in original).[27]

Name. 21 C.F.R. § 102.33 addresses how a juice manufacturer can name a multi-juice beverage.[28] Under paragraph (b), the name need not include the individual juices in descending order by volume if "the name specifically shows that the juice with the represented flavor is used as a flavor (e.g., raspberry-flavored apple and pear juice drink)." Under paragraph (c), the name need not include all the single-strength juices if the name "indicate[s] that the represented juice is not the only juice present (e.g., 'Apple blend; apple juice in a blend of two other fruit juices.')." And under paragraph (d), the named single-

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[27] Even if FDA is entitled to deference concerning interpretation of its regulations, it is not entitled to deference concerning the interplay between those regulations and a separate federal law (the Lanham Act) that FDA does not administer, see, *e.g.*, *U.S. Air Tour Ass'n* v. *FAA*, 298 F.3d 997, 1015-16 (D.C. Cir. 2002), or the ultimate question whether the FDCA provisions and/or FDA regulations preclude a Lanham Act claim, cf. *PLIVA*, 131 S. Ct. at 2575 n.3 ("we do not defer to an agency's ultimate conclusion about whether state law should be pre-empted").

[28] 21 C.F.R. § 102.5(b) (discussed at Pet. Br. 51) precedes § 102.33 and sets forth "[g]eneral principles" for Part 102 of 21 C.F.R. Chapter I, Subchapter B. Section 102.5(b) makes clear that its general principles apply "unless modified by a specific regulation in subpart B of this part," 21 C.F.R. § 102.5(b), such as § 102.33.

strength juices need not be the predominant one if the name either "(1) [i]ndicate[s] that the named juice is present as a flavor or flavoring (e.g., 'Raspcranberry'; raspberry and cranberry flavored juice drink); or (2) [i]nclude[s] the amount of the named juice, declared in a 5-percent range ...."

Each of these paragraphs applies here and authorizes the name respondent chose: "POMEGRANATE BLUEBERRY FLAVORED BLEND OF 5 JUICES ..." JA 38a. The name is a precise aggregation of the cited example names in § 102.33(b)-(d), using the term "flavored," the term "blend of _ juices," and the names of the minority juices.[29]

To be sure, § 102.33(d) allows a manufacturer to choose between using a name like "POMEGRANATE BLUEBERRY FLAVORED BLEND OF 5 JUICES ..." and disclosing the percentage contribution of the named single-strength juice to the beverage as a whole. See Pet. Br. 23. And FDA stated in the rulemaking statement that it "affirmatively 'encourage[s]' that 'each juice in a beverage be declared in the name of the product.'" Pet. Br. 36 (quoting 58 Fed. Reg. 2897, 2919 (Jan. 6, 1993)) (alteration in original). But FDA did not *require* such a declaration and instead left the choice to the manufacturer, cf. *Geier* v. *Am. Honda Motor Co.*, 529 U.S. 861, 874-75 (2000), in keeping with FDA's recognition, in a rulemaking statement issued on the same day § 102.33 was adopted, that, "even though Federal requirements may preempt

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[29] Even if the product's label did not satisfy § 102.33 or the other regulatory provisions discussed below, it would not follow that petitioner's Lanham Act claim should be allowed. Rather, any non-compliance by respondent with that FDCA scheme is a matter for FDA (or in limited instances the States) to enforce under 21 U.S.C. § 337.

more restrictive State requirements in certain instances, the net benefits from national uniformity in these aspects of the food label outweigh the loss in consumer protection that may occur as a result." 58 Fed. Reg. at 2462. Petitioner's proposed regime in which private plaintiffs across the country can seek divergent standards would destroy the national uniformity that Congress sought to attain. See *supra*, at 2.

Nor, contrary to petitioner's suggestion (Br. 23), is there any *de minimis* exception to the naming rules of § 102.33, such that where the percentage contribution of the named single-strength juice is quite small, those rules no longer apply. Not only is such an exception absent from the text of § 102.33, but that text actually contemplates, see § 102.33(b) (citing 21 C.F.R. § 101.22(i)(1)(iii)), the situation where the percentage contribution of the named juice is so small that it does not itself suffice to be the characterizing flavor without the addition of additional flavoring that "simulates, resembles or reinforces the characterizing flavor." 21 C.F.R. § 101.22(i)(1)(iii). See also 58 Fed. Reg. at 2921 (recognizing that § 102.33(d)'s option of using "flavored" to indicate presence of non-named fruit juices would apply even where the named juice that precedes "flavored" is "less than 2 percent" of the beverage).

Petitioner finally argues that, "[b]ecause pomegranate juice and blueberry juice are not 'present as a flavor' as required by § 102.33(d), respondent cannot invoke that provision to show that its product's name complies with FDA's juice-naming regulations." Br. 50 (quoting 21 C.F.R. § 102.33(d)(1)). As an initial matter, this argument is waived because petitioner did not raise it in the courts below. See, *e.g.*, *Cutter* v.

Wilkinson, 544 U.S. 709, 718 n.7 (2005). In any event, the argument is incorrect because it assumes that the relevant regulation, § 102.33(d)(1), allows the name to include a non-predominant juice only if the *juice* (here, .3% and .2% pomegranate and blueberry juice concentrates, respectively) is *the* dispositive, characterizing flavoring agent. In fact, § 102.33(d)(1) does not so require; rather, the "juice" need only be "present as *a* flavor or flavoring," 21 C.F.R. § 102.33(d)(1) (emphasis added), and can be reinforced by added flavors (such as "essential oil[s]" or "extractive[s]," *id.* § 101.22(a)(3)) that, together with the juice(s), make the product taste like the named fruits.[30]

As to whether the juices-plus-added-flavors in fact make the product here taste like pomegranate and blueberry, a question raised by § 102.33(b) (where "the declared juices alone do not characterize the product before the addition of ... added [natural] flavors," "the presence of added natural flavors is ... required to be declared"), respondent answered "yes" through the words "AND OTHER NATURAL FLAVORS" (JA 38a),

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[30] The United States suggests (Br. 23, expressly departing from its certiorari-stage brief, see *id.* at 23 n.8 (so acknowledging)) that there may be a remaining factual question "whether pomegranate and blueberry juices in respondent's product are present as flavors or flavoring," but the United States should not be allowed to overcome petitioner's waiver of this issue. See *FTC* v. *Phoebe Putney Health Sys., Inc.*, 568 U.S. __, 133 S. Ct. 1003, 1010 n.4 (2013). In any event, pomegranate and blueberry juices (without added flavors) need not be *the* crucial flavoring agents as a matter of law for the reasons discussed in text, and that pomegranate juice and blueberry juice are each *a* flavor is clear from the absence of any statement on the label that these juices have been "deflavored," 21 C.F.R. § 102.33(e). Thus, contrary to the United States' suggestion, there is no need for remand for any factual development on this question.

and petitioner appears to agree, see Br. 50 ("It is added 'natural flavoring'—not actual pomegranate and blueberry *juice*—that (allegedly) gives the product a pomegranate-blueberry flavor.") (footnote omitted). At the very least, petitioner does not affirmatively dispute that factual proposition; the word "(allegedly)" surely cannot be enough to do so, especially where petitioner never asserted such an argument below.

Font sizes. Section 102.33(b)'s cross-reference to § 101.22(i)(1)(iii), which both petitioner and the United States ignore, specifically authorizes the sizes respondent chose for "POMEGRANATE" and "BLUEBERRY," on the one hand, and "FLAVORED BLEND OF 5 JUICES," on the other. As discussed above, § 102.33(b) allows the name to omit any list of single-strength juices in descending order by volume, and instead to declare a minority juice first, "e.g., raspberry-flavored apple and pear juice drink." 21 C.F.R. § 102.33(b). Section 102.33(b) then cross-references § 101.22(i)(1)(iii) as follows: "In accordance with § 101.22(i)(1)(iii) of this chapter, the presence of added natural flavors is not required to be declared in the name of the beverage unless the declared juices alone do not characterize the product before the addition of the added flavors." *Id.* § 102.33(b). And § 101.22(i)(1)(iii) in turn provides that, where the manufacturer *does* need to add such added flavors, "the name of the food shall be immediately followed by the words 'with other natural flavor' *in letters not less than one-half the height of the letters used in the name of the characterizing flavor.*" *Id.* § 101.22(i)(1)(iii) (emphasis added). Section 102.33(b)'s cross-reference to § 101.22(i)(1)(iii) thus instructs that the words "flavored apple and pear juice drink" in the § 102.33(b) example must be not less than one-half the height of the word "raspberry," and, here, that

"FLAVORED BLEND OF FIVE JUICES" must be not less than one-half the height of "POMEGRANATE" and "BLUEBERRY."[31] As is evident from JA 38a, respondent's label meets this requirement.[32]

Even aside from § 102.33(b)'s cross-reference to § 101.22(i)(1)(iii), the "not less than one-half the height" requirement applies to the word "FLAVORED" (and hence logically to the words "BLEND OF 5 JUICES" that appear on the same line as "FLAVORED") by virtue of § 101.22(i)(1)(i). That regulation, it will be recalled, applies where "the food is one that is commonly expected to contain a characterizing food ingredient, e.g., strawberries in 'strawberry shortcake,' and the food contains natural flavor derived from such ingredient and an amount of characterizing ingredient insufficient to independently characterize the food[.]" 21 C.F.R. § 101.22(i)(1)(i). It further provides that, in such a circumstance, "the name of the characterizing flavor ... shall be immediately followed by the word 'flavored' in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g., ... 'strawberry flavored shortcake.'" *Ibid.* It applies here because, in

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[31] The cross-reference makes sense. The added flavors addressed by § 101.22(i)(1)(iii), like the non-named single-strength juices (here, apple, grape, and raspberry) addressed by § 102.33, are ingredients other than pomegranate and blueberry that need not be disclosed individually and instead may be referenced through words that follow "POMEGRANATE BLUEBERRY"—namely, through the words "FLAVORED BLEND OF 5 JUICES" (to satisfy § 102.33) and "OTHER NATURAL FLAVORS" (to satisfy § 101.22(i)(1)(iii)).

[32] Only by ignoring § 102.33(b)'s cross-reference to § 101.22(i)(1)(iii) is the United States able to assert (Br. 33) that the regulations at most provide the required height size for the word "FLAVORED" and not the words "BLEND OF 5 JUICES."

addition to the pomegranate juice concentrate and blueberry juice concentrate ingredients, the beverage contains natural pomegranate flavoring and natural blueberry flavoring. See JA 39a. As noted above, the words "FLAVORED BLEND OF 5 JUICES" are more than half the height of the words "POMEGRANATE BLUEBERRY" and hence comply with § 101.22(i)(1)(i).[33]

Finally, even if the "not less than one-half the height" requirement does not apply to § 102.33, it does not follow that FDA's regulations are silent on the issue. To the contrary, respondent's label would still be governed by (and comply with) 21 C.F.R. § 101.3(d): "This statement of identity"—here, the name, see § 101.3(b)—"shall be presented in bold type on the principal display panel, shall be in a size reasonably related to the most prominent printed matter on such panel, and shall be in lines generally parallel to the

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[33] Section 101.22(i)(1)(iii) also directly applies here (*i.e.*, even aside from the fact that it is cross-referenced by § 102.33(b)) because, in addition to the pomegranate juice concentrate and blueberry juice concentrate ingredients, the beverage contains other (*i.e.*, not pomegranate or blueberry) natural flavoring that simulates, resembles, or reinforces the overall pomegranate and blueberry flavors. See JA 39a. In keeping with § 101.22(i)(1)(iii), the "name of the food" is "immediately followed by the words 'with ... other natural flavor[s]' [in caps, JA 38a] in letters not less than one-half the height of the letters used in the name of the characterizing flavor [*i.e.*, pomegranate and blueberry, in caps, JA 38a]." *Id.* § 101.22(i)(1)(iii). The "immediately followed" requirement is met because the name of the product consists not only of the words "POMEGRANATE BLUEBERRY FLAVORED BLEND OF 5 JUICES" but also the words "FROM CONCENTRATE WITH ADDED INGREDIENTS," see *id.* §§ 102.33(g)(1), 101.30(b)(3), and those words are immediately followed by "AND OTHER NATURAL FLAVORS." Petitioner's contrary argument (Br. 50-51) ignores these regulations.

base on which the package rests as it is designed to be displayed."

As with the naming rules, the font-size rules—the "not less than one-half the height" requirement and/or the "size reasonably related to the most prominent printed matter" requirement—allow the manufacturer to choose its own nationally-uniform label within the bounds set by these requirements. The contrary regime proposed by petitioner and the United States again would allow private plaintiffs across the nation to seek a phalanx of divergent standards, disrupting Congress's national-uniformity goal. See *supra*, at 2. The United States' brief ignores FDA's recognition and endorsement, see 58 Fed. Reg. at 2462, of that national-uniformity goal.

Vignette. Petitioner waived this issue by raising it only in a footnote in its opening brief in the court of appeals, see Br. for Appellant, *supra* n. 6, at 28 n.11, after which the court specifically declined to address it because it was "not meaningfully" (Pet. App. 10a) raised. See, *e.g.*, *Sosa* v. *Alvarez-Machain*, 542 U.S. 692, 735 n.24 (2004) (A "footnote ... is not enough to raise the question fairly, and we do not consider it.").[34]

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[34] The United States acknowledges the waiver but, contrary to its position in other cases, does not affirmatively argue that this Court should find the vignette issue waived. Compare U.S. Br. 30 n.14, with Brief for the United States as *Amicus Curiae* Supporting Respondent at 29, *Robertson* v. *United States*, 560 U.S. 272 (2010) (No. 08-6261), 2010 WL 783666 ("[I]t would be particularly inappropriate [to consider an argument waived by petitioner] because petitioner's waiver ... means that the D.C. Court of Appeals never had an opportunity to answer key questions about the [relevant facts]."). The United States should not be allowed to inject this waived argument into the case. See *Phoebe Putney Health Sys.*, 133 S. Ct. at 1010 n.4.

In any event, FDA's rulemaking authorizes this aspect of respondent's label as well. Specifically, some commenters (to FDA's proposed rule) requested "that the fruits ... be depicted in proportion to the amount of each juice present." 58 Fed. Reg. at 2922. FDA rejected that proposal because, *inter alia*, "the relative size and the quantity of those fruits ... are difficult to represent in a manner that would allow the consumer to readily recognize the quantity relationship." *Ibid.*

FDA thus again left manufacturers with the ability to include a vignette of their choosing that could be employed nationwide. Private Lanham Act suits seeking to impose idiosyncratic vignette requirements would disrupt national uniformity in contravention of Congress's intent. Petitioner might want a vignette that depicts a tiny pomegranate and blueberries relative to a larger apple and grapes; another plaintiff might insist on including percentage components below the vignette; another plaintiff might seek a ban on vignettes altogether. To the extent FDA left open the possibility of "case-by-case" analysis, 58 Fed. Reg. at 2922, it meant analysis by "*[t]he agency*," *ibid.* (emphasis added), not by private Lanham Act plaintiffs. Moreover, respondent's vignette actually serves to make the label less, not more, misleading insofar as it depicts all five fruits, and thus underscores to consumers the message sent by "FLAVORED BLEND OF 5 JUICES," JA 38a, *i.e.*, that pomegranate and blueberry are not the only juices present. See 58 Fed. Reg. at 2921-22 (refusing to require that vignette depict all fruits, but noting that doing so "would provide useful information").

Division of name onto multiple lines. Petitioner waived this argument (Br. 23) as well, raising the argument only in a footnote in its opening brief in the

court of appeals, see Br. for Appellant, *supra* n. 6, at 28 n.11, and the court of appeals did not address it. See *Cutter*, 544 U.S. at 718 n.7 ("Because these [arguments] were not addressed by the Court of Appeals, and mindful that we are a court of review, not of first view, we do not consider them here.").[35]

In any event, this aspect of respondent's label is authorized by FDA's regulation acknowledging that the name may appear "in *lines*." 21 C.F.R. § 101.3(d) (emphasis added). FDA could have but did not mandate that the name appear on a single line, a requirement that would be impractical because "[s]ome juice beverages will have very complex common or usual names." FDA, *A Food Labeling Guide* 11 (Jan. 2013), *available at* http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM265446.pdf. Again, if private Lanham Act suits are allowed on this issue, the potential for divergent standards is manifest: One plaintiff might seek to require that the entire name appear on the same line, another plaintiff might be amenable to having the name on two but not more lines, yet another plaintiff might be indifferent as to the number of lines so long as they appear within a bold highlighted box.

Coloring. Petitioner waived this argument (Br. 2, 23-24) by failing to raise it in any fashion before the court of appeals panel, which consequently did not

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[35] While the United States at least acknowledges petitioner's waiver problem regarding the vignette, *see supra* at 45 n. 34, the United States (Br. 33) fails to recognize that the same problem exists as to petitioner's "division onto multiple lines" argument, and indeed the United States affirmatively advances (*ibid.*) this argument on the merits. The United States again should not be allowed to inject this waived argument into the case. See *Phoebe Putney Health Sys.*, 133 S. Ct. at 1010 n.4.

address it.[36] In any event, FDA's regulation specifies that the "statement of ingredients," 21 C.F.R. § 101.22(k)—as opposed to the front label—must declare color additives of the type here using terms such as "'Color Added,'" "'Colored with __,'" or "an equally informative term that makes clear that a color additive has been used in the food," *id.* § 101.22(k)(2). Respondent's statement of ingredients complies by including "FRUIT AND VEGETABLE JUICES (FOR COLOR)." JA 39a. Petitioner and other private plaintiffs may not impose different standards.

It is evident from the foregoing discussion that the FDCA and FDA regulations, on the one hand, and a Lanham Act suit like petitioner's, on the other, seek to regulate the same thing—the name and label of a juice beverage—in non-identical ways. Petitioner's argument (Br. 25-26) that the supposedly distinct purposes of the FDCA/NLEA and the Lanham Act eliminate this tension is incorrect. To begin with, both the FDCA and the Lanham Act share the goal of preventing consumers from being deceived. Compare, *e.g.*, 21 U.S.C. § 341 (FDCA "promote[s] honesty and fair dealing in the interest of consumers"), with *Am. Home Prods. Corp.* v. *Johnson & Johnson*, 577 F.2d 160, 165 (2d Cir. 1978) (Lanham Act § 43(a) seeks to "protect[] against ... sophisticated deception" as "tested by the reactions of the public").[37] Moreover,

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[36] The United States discusses neither the waiver nor the merits aspects of petitioner's coloring argument.

[37] In contrast, the different laws in the cases cited by petitioner (Br. 25) did not regulate the same subject matter. See, *e.g.*, *J.E.M. Ag Supply, Inc.* v. *Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 144 (2001) (laws only "partial[ly]" "overlap[ped]"); *Bd. of Sup'rs of Wood Cnty.* v. *Lackawana Iron & Coal Co.*, 93 U.S. 619, 622

regardless of the Lanham Act's underlying policies, the greater stringency that private plaintiffs might seek under that Act directly undermines Congress's intent in the FDCA/NLEA. As FDA recognized, "in enacting the [NLEA], Congress decided that even though Federal requirements might preempt more restrictive State requirements in certain instances, the net benefits from national uniformity in these aspects of the food label outweigh the loss in consumer protection that may occur as a result." 58 Fed. Reg. at 2462.

III. PETITIONER'S REMAINING ARGUMENTS ARE UNPERSUASIVE

Petitioner concludes (Br. 52-56) with a plea that its Lanham Act claim should be allowed because, *first*, FDA supposedly lacks resources to regulate food naming and labeling, and *second*, finding the Lanham Act claim precluded here will allegedly require the same outcome in numerous non-food sectors. Neither argument has merit.

A. FDA Determined That The Relevant FDCA Provisions Were Adequately Implemented, And In Any Event National Uniformity Was Congress's Overriding Goal

Petitioner asserts (without basis) that FDA lacks adequate resources without explaining why that issue is legally relevant. For several reasons, it is not.

First, as discussed *supra*, at 7, in 1993, FDA certified that FDCA § 403(f) and (i)(1) were "adequately implemented." 58 Fed. Reg. at 2473-74. The NLEA

(1876) (laws applied to different companies and geographic areas).

does not prescribe any mechanism for FDA to retract that determination. Accordingly, it is that determination, and not the reports cited by petitioner (Br. 53-54) and its *amicus* Donald Kennedy (Br. 7-11), that is dispositive here. Tellingly, the United States' brief (signed by several officials of HHS (of which FDA is a part)) does not suggest that FDA's resources are inadequate.

Second, FDA, even aside from its "adequately implemented" certification, has engaged in robust enforcement of the FDCA's food naming/labeling provisions, issuing numerous warning letters relating to food each year. See FDA, Inspections, Compliance, Enforcement, and Criminal Investigations: Warning Letters, http://www.fda.gov/iceci/enforcementactions/WarningLetters/default.htm (search for "food labeling").[38] Mr. Kennedy diminishes such letters as "typically the extent of [FDA's] enforcement activity" (Kennedy Br. 9 (internal quotation marks omitted)), but he does not explain why they are insufficient. In fact, according to FDA, they are highly successful. See Office of Inspector General, Dep't of Health and Human Services, FDA Warning Letters—Timeliness and Effectiveness 2 (Feb. 1999), *available at* https://oig.hhs.gov/oei/reports/oei-09-97-00381.pdf ("When FDA conducts follow-up activities, it finds that firms have either corrected the violations cited in warning letters or have made significant progress toward doing so. Almost 90 percent of firms respond in writing to warning letters within 15 days of receiving them,

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[38] Petitioner itself has been a recipient. See Letter from FDA to Matt Tupper, dated February 23, 2010, *available at* http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm202785.htm.

detailing corrective actions that they intend to take.").[39]

Third, even if FDA lacked resources to regulate food naming and labeling, it does not follow that allowing private Lanham Act claims is the solution Congress intended. To the contrary, Congress recognized that private suits would beget a worse problem by subjecting food manufacturers to a patchwork of constantly shifting standards across the country. And it was *that* problem that Congress deemed paramount and sought to resolve in enacting the NLEA's "national uniform[ity]" provision. In FDA's words, "Congress decided that ... the net benefits from national uniformity in these aspects of the food label outweigh the loss in consumer protection that may occur as a result." 58 Fed. Reg. at 2462.[40] Cf. *Astra*, 131 S. Ct. at 1350 (despite reports "of inadequate [agency] enforcement," "Congress did not respond ... by inviting 340B entities to launch lawsuits in district courts across the country").

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[39] *Amici curiae* Public Citizen *et al.* incorrectly assert (Br. 21) that FDA issued only one warning letter from February 1, 2013 to February 1, 2014 regarding food labeled in a misleading manner. See also Letter from FDA to Cheryl Stewart, dated March 28, 2013, *available at* http://www.fda.gov/iceci/enforcementactions/warningletters/2013/ucm346316.htm; Letter from FDA to Riad Shatila, dated March 6, 2013, *available at* http://www.fda.gov/iceci/enforcementactions/warningletters/2013/ucm354203.htm. Moreover, *amici* have not shown that additional instances occurred that escaped a warning letter.

[40] *Amici* States, in dismissing national uniformity as a "sub-goal" (Alaska Br. 21), ignore this FDA statement, the title of the NLEA's preemption clause, and the legislative history. *Amici* States, unlike private plaintiffs, enjoy certain rights to enforce the FDCA, 21 U.S.C. § 337(b), and to seek exemptions from the NLEA's preemption clause, *id.* § 343-1(b).

B. Preclusion Of Petitioner's Lanham Act Claim As To The Juice Naming And Labeling Issues Here Will Not Curtail The Lanham Act In Other Circumstances

Contrary to petitioner's exaggerated assertion (Br. 55), a holding that its Lanham Act claim is precluded under the circumstances here will not "preclude a Lanham Act suit ... in any regulated field." As an initial matter, a Lanham Act § 43(a) claim would not even be precluded in all circumstances involving food labeling. For example, because there is no FDCA provision on religious dietary labeling, see 56 Fed. Reg. at 60530, and certainly no such provision that has preemptive force under the NLEA's pre-emption clause, a private plaintiff could sue under Lanham Act § 43(a) if its competitor falsely labeled its product "kosher" or "halal."

Nor will Lanham Act § 43(a) suits be precluded in the other areas that petitioner cites (Br. 54-55) as examples, apart perhaps from cosmetics labeling. See Br. 54-55 (citing *Astiana* v. *Hain Celestial Group, Inc.*, 905 F. Supp. 2d 1013, 1014 (N.D. Cal. 2012)). Although that court did not address the question, the portion of the FDCA at issue contains an express preemption clause, 21 U.S.C. § 379s, similar to the NLEA's, such that the analysis in Point II.B, *supra*, may suggest preclusion of a Lanham Act claim.[41]

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[41] On the other hand, unlike in 21 U.S.C. § 343-1, Congress did not postpone the effectiveness of 21 U.S.C. § 379s until the agency had determined that the provisions to be given preemptive force were adequately implemented. Additionally, the analysis in Point II.C, *supra*, would not apply because FDA had not engaged in any detailed regulation of use of the words "all natural," "pure

As to petitioner's second example (Br. 55), the Organic Food Products Act does not contain an express preemption clause, rendering inapplicable the analysis in Point II.B, *supra*, and the agency had not yet issued a regulation authorizing the use of the ingredients in the product, rendering inapplicable the analysis in Point II.C, *supra*.

Petitioner's final example (Br. 55) is easily dispatched. The FTC Act, unlike the FDCA, contains an explicit provision that the FTC Act should not "be construed to prevent or interfere with the enforcement of the provisions of," or "to alter, modify or repeal," "the antitrust Acts or the Acts to regulate commerce." 15 U.S.C. § 51. See also *id.* § 1127 (Lanham Act "regulate[s] commerce"). Congress has thus directed that the FTC Act should *not* foreclose a claim under the Lanham Act.[42] By contrast, the FDCA and NLEA contain no such savings clause, and they do contain an express preemption clause that reveals Congress's intent to promote national uniformity and to bar suits by private plaintiffs that would undermine national uniformity.

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natural," and "pure, natural & organic," and thus the defendant could not argue that its product label was authorized by FDA's regulations.

[42] Moreover, the "regulatory guides" petitioner cites (Br. 55), unlike the FDCA provisions and FDA regulations at issue, provide the basis for "*voluntary* [compliance]," 16 C.F.R. pt. 17 (emphasis added), and thus "lack the force of law," *Christensen* v. *Harris Cnty.*, 529 U.S. 576, 587 (2000).

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

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March 26, 2014

APPENDIX

APPENDIX

1. Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, § 6, 104 Stat. 2353, 2362-64 provides:

Sec. 6. NATIONAL UNIFORM NUTRITION LABELING.

(a) PREEMPTION.—Chapter IV is amended by adding after section 403 the following new section:

SEC. 403A. (a) Except as provided in subsection (b), no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—

(1) any requirement for a food which is the subject of a standard of identity established under section 401 that is not identical to such standard of identity or that is not identical to the requirement of section 403(g),

(2) any requirement for the labeling of food of the type required by section 403(c), 403(e), or 403(i)(2) that is not identical to the requirement of such section,

(3) any requirement for the labeling of food of the type required by section 403(b), 403(d), 403(f), 403(h), 403(i)(1), or 403(k) that is not identical to the requirement of such section,

(4) any requirement for nutrition labeling of food that is not identical to the requirement of section 403(q), except a requirement for nutrition labeling of food which is exempt under subclause (i) or (ii) of section 403(q)(5)(A), or

(5) any requirement respecting any claim of the type described in section 403(r)(1) made in the label

or labeling of food that is not identical to the requirement of section 403(r), except a requirement respecting a claim made in the label or labeling of food which is exempt under clause (B) of such section.

Paragraph (3) shall take effect in accordance with section 6(b) of the Nutrition Labeling and Education Act of 1990.

(b) Upon petition of a State or a political subdivision of a State, the Secretary may exempt from subsection (a), under such conditions as may be prescribed by regulation, any State or local requirement that—

(1) would not cause any food to be in violation of any applicable requirement under Federal law,

(2) would not unduly burden interstate commerce, and

(3) is designed to address a particular need for information which need is not met by the requirements of the sections referred to in subsection (a).

(b) STUDY AND REGULATIONS.—

(1) For the purpose of implementing section 403A(a)(3), the Secretary of Health and Human Services shall enter into a contract with a public or nonprofit private entity to conduct a study of—

(A) State and local laws which require the labeling of food that is of the type required by sections 403(b), 403(d), 403(f), 403(h), 403(i)(1), and 403(k) of the Federal Food, Drug, and Cosmetic Act, and

(B) the sections of the Federal Food, Drug, and Cosmetic Act referred to in subparagraph (A) and the regulations issued by the Secretary to

enforce such sections to determine whether such sections and regulations adequately implement the purposes of such sections.

(2) The contract under paragraph (1) shall provide that the study required by such paragraph shall be completed within 6 months of the date of the enactment of this Act.

(3)(A) Within 9 months of the date of the enactment of this Act, the Secretary shall publish a proposed list of sections which are adequately being implemented by regulations as determined under paragraph (1)(B) and sections which are not adequately being implemented by regulations as so determined. After publication of the lists, the Secretary shall provide 60 days for comments on such lists.

(B) Within 24 months of the date of the enactment of this Act, the Secretary shall publish a final list of sections which are adequately being implemented by regulations and a list of sections which are not adequately being implemented by regulations. With respect to a section which is found by the Secretary to be adequately implemented, no State or political subdivision of a State may establish or continue in effect as to any food in interstate commerce any requirement which is not identical to the requirement of such section.

(C) Within 24 months of the date of the enactment of this Act, the Secretary shall publish proposed revisions to the regulations found to be inadequate under subparagraph (B) and within 30 months of such date shall issue final revisions. Upon the effective date of such final revisions, no State or political subdivision may establish or continue in

effect any requirement which is not identical to the requirement of the section which had its regulations revised in accordance with this subparagraph.

(D)(i) If the Secretary does not issue a final list in accordance with subparagraph (B), the proposed list issued under subparagraph (A) shall be considered the final list and States and political subdivisions shall be preempted with respect to sections found to be adequate in such proposed list in accordance with subparagraph (B).

(ii) If the Secretary does not issue final revisions of regulations in accordance with subparagraph (C), the proposed revisions issued under such subparagraph shall be considered the final revisions and States and political subdivisions shall be preempted with respect to sections the regulations of which are revised by the proposed revisions.

(E) Subsection (b) of section 403A of the Federal Food, Drug, and Cosmetic Act shall apply with respect to the prohibition prescribed by subparagraphs (B) and (C).

(c) CONSTRUCTION.—

(1) The Nutrition Labeling and Education Act of 1990 shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under section 403A of the Federal Food, Drug, and Cosmetic Act.

(2) The amendment made by subsection (a) and the provisions of subsection (b) shall not be construed to apply to any requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food.

(3) The amendment made by subsection (a), the provisions of subsection (b) and paragraphs (1) and (2) of this subsection shall not be construed to affect preemption, express or implied, of any such requirement of a State or political subdivision, which may arise under the Constitution, any provision of the Federal Food, Drug, and Cosmetic Act not amended by subsection (a), any other Federal law, or any Federal regulation, order, or other final agency action reviewable under chapter 7 of title 5, United States Code.

2. 21 U.S.C. § 343-1 provides:

National uniform nutrition labeling

(a) Except as provided in subsection (b) of this section, no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—

(1) any requirement for a food which is the subject of a standard of identity established under section 341 of this title that is not identical to such standard of identity or that is not identical to the requirement of section 343(g) of this title, except that this paragraph does not apply to a standard of identity of a State or political subdivision of a State for maple syrup that is of the type required by sections 341 and 343(g) of this title,

(2) any requirement for the labeling of food of the type required by section 343(c), 343(e), 343(i)(2), 343(w), or 343(x) of this title that is not identical to the requirement of such section, except that this paragraph does not apply to a requirement of a State or political subdivision of a State

that is of the type required by section 343(c) of this title and that is applicable to maple syrup,

(3) any requirement for the labeling of food of the type required by section 343(b), 343(d), 343(f), 343(h), 343(i)(1), or 343(k) of this title that is not identical to the requirement of such section, except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 343(h)(1) of this title and that is applicable to maple syrup,

(4) any requirement for nutrition labeling of food that is not identical to the requirement of section 343(q) of this title, except that this paragraph does not apply to food that is offered for sale in a restaurant or similar retail food establishment that is not part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership of the locations) and offering for sale substantially the same menu items unless such restaurant or similar retail food establishment complies with the voluntary provision of nutrition information requirements under section 343(q)(5)(H)(ix) of this title, or

(5) any requirement respecting any claim of the type described in section 343(r)(1) of this title made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title, except a requirement respecting a claim made in the label or labeling of food which is exempt under section 343(r)(5)(B) of this title.

Paragraph (3) shall take effect in accordance with section 6(b) of the Nutrition Labeling and Education Act of 1990.

(b) Upon petition of a State or a political subdivision of a State, the Secretary may exempt from subsection (a) of this section, under such conditions as may be prescribed by regulation, any State or local requirement that—

(1) would not cause any food to be in violation of any applicable requirement under Federal law,

(2) would not unduly burden interstate commerce, and

(3) is designed to address a particular need for information which need is not met by the requirements of the sections referred to in subsection (a) of this section.

3. 21 U.S.C. § 321 provides in pertinent part:

Definitions; generally

* * * * *

(f) The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(n) If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the

labeling or advertising thereof or under such conditions of use as are customary or usual.

* * * * *

4. 21 U.S.C. § 337 provides:

Proceedings in name of United States; provision as to subpoenas

(a) Except as provided in subsection (b) of this section, all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

(b)(1) A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 341, 343(b), 343(c), 343(d), 343(e), 343(f), 343(g), 343(h), 343(i), 343(k), 343(q), or 343(r) of this title if the food that is the subject of the proceedings is located in the State.

(2) No proceeding may be commenced by a State under paragraph (1)—

(A) before 30 days after the State has given notice to the Secretary that the State intends to bring such proceeding,

(B) before 90 days after the State has given notice to the Secretary of such intent if the Secretary has, within such 30 days, commenced an informal or formal enforcement action pertaining to the food which would be the subject of such proceeding, or

(C) if the Secretary is diligently prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled the informal or formal enforcement action pertaining to such food.

In any court proceeding described in subparagraph (C), a State may intervene as a matter of right.

5. 21 U.S.C. § 343 provides in pertinent part:

Misbranded food

A food shall be deemed to be misbranded—

(a) False or misleading label

If (1) its labeling is false or misleading in any particular, * * *

* * * * *

(f) Prominence of information on label

If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

* * * * *

(i) Label where no representation as to definition and standard of identity

Unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient and if the food purports to be a beverage containing vegetable or fruit

juice, a statement with appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice contained in the food; except that spices, flavorings, and colors not required to be certified under section 379e(c)[1] of this title unless sold as spices, flavorings, or such colors, may be designated as spices, flavorings, and colorings without naming each. To the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

* * * * *

6. 15 U.S.C. § 1125 provides in pertinent part:

False designations of origin, false descriptions, and dilution forbidden

(a) Civil action

(1) Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which—

(A) is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person, or

(B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or

---

[1] So in original. Probably should be followed by a comma.

geographic origin of his or her or another person's goods, services, or commercial activities,

shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

* * * * *

7. 21 C.F.R. § 101.3 provides in pertinent part:

Identity labeling of food in packaged form.

(a) The principal display panel of a food in package form shall bear as one of its principal features a statement of the identity of the commodity.

(b) Such statement of identity shall be in terms of:

(1) The name now or hereafter specified in or required by any applicable Federal law or regulation; or, in the absence thereof,

(2) The common or usual name of the food; or, in the absence thereof,

(3) An appropriately descriptive term, or when the nature of the food is obvious, a fanciful name commonly used by the public for such food.

* * * * *

(d) This statement of identity shall be presented in bold type on the principal display panel, shall be in a size reasonably related to the most prominent printed matter on such panel, and shall be in lines generally parallel to the base on which the package rests as it is designed to be displayed.

* * * * *

8. 21 C.F.R. § 101.4 provides in pertinent part:

Food; designation of ingredients.

(a)(1) Ingredients required to be declared on the label or labeling of a food, including foods that

comply with standards of identity, except those ingredients exempted by 101.100, shall be listed by common or usual name in descending order of predominance by weight on either the principal display panel or the information panel in accordance with the provisions of 101.2, except that ingredients in dietary supplements that are listed in the nutrition label in accordance with 101.36 need not be repeated in the ingredient list. * * *

* * * * *

9. 21 C.F.R. § 101.22 provides in pertinent part:

Foods; labeling of spices, flavorings, colorings and chemical preservatives.

* * * * *

(a)(3) The term *natural flavor* or *natural flavoring* means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional. Natural flavors include the natural essence or extractives obtained from plants listed in §§ 182.10, 182.20, 182.40, and 182.50 and part 184 of this chapter, and the substances listed in § 172.510 of this chapter.

* * * * *

(i) If the label, labeling, or advertising of a food makes any direct or indirect representations with

respect to the primary recognizable flavor(s), by word, vignette, e.g., depiction of a fruit, or other means, or if for any other reason the manufacturer or distributor of a food wishes to designate the type of flavor in the food other than through the statement of ingredients, such flavor shall be considered the characterizing flavor and shall be declared in the following way:

(1) If the food contains no artificial flavor which simulates, resembles or reinforces the characterizing flavor, the name of the food on the principal display panel or panels of the label shall be accompanied by the common or usual name of the characterizing flavor, e.g., "vanilla", in letters not less than one-half the height of the letters used in the name of the food, except that:

(i) If the food is one that is commonly expected to contain a characterizing food ingredient, e.g., strawberries in "strawberry shortcake", and the food contains natural flavor derived from such ingredient and an amount of characterizing ingredient insufficient to independently characterize the food, or the food contains no such ingredient, the name of the characterizing flavor may be immediately preceded by the word "natural" and shall be immediately followed by the word "flavored" in letters not less than one-half the height of the letters in the name of the characterizing flavor, e.g., "natural strawberry flavored shortcake," or "strawberry flavored shortcake".

(ii) If none of the natural flavor used in the food is derived from the product whose flavor is simulated, the food in which the flavor is used shall be labeled either with the flavor of the product from which the flavor is derived or as "artificially flavored."

(iii) If the food contains both a characterizing flavor from the product whose flavor is simulated and other natural flavor which simulates, resembles or reinforces the characterizing flavor, the food shall be labeled in accordance with the introductory text and paragraph (i)(1)(i) of this section and the name of the food shall be immediately followed by the words "with other natural flavor" in letters not less than one-half the height of the letters used in the name of the characterizing flavor.

* * * * *

(k) The label of a food to which any coloring has been added shall declare the coloring in the statement of ingredients in the manner specified in paragraphs (k)(1) and (k)(2) of this section, except that colorings added to butter, cheese, and ice cream, if declared, may be declared in the manner specified in paragraph (k)(3) of this section, and colorings added to foods subject to 105.62 and 105.65 of this chapter shall be declared in accordance with the requirements of those sections.

* * * * *

(2) Color additives not subject to certification and not otherwise required by applicable regulations in part 73 of this chapter to be declared by their respective common or usual names may be declared as "Artificial Color," "Artificial Color Added," or "Color Added" (or by an equally informative term that makes clear that a color additive has been used in the food). Alternatively, such color additives may be declared as "Colored with _____" or "_____ color," the blank to be filled in with the name of the color additive listed in the applicable regulation in part 73 of this chapter.

* * * * *

10. 21 C.F.R. § 102.5 provides in pertinent part:

General principles.

(a) The common or usual name of a food, which may be a coined term, shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients. The name shall be uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name. Each class or subclass of food shall be given its own common or usual name that states, in clear terms, what it is in a way that distinguishes it from different foods.

(b) The common or usual name of a food shall include the percentage(s) of any characterizing ingredient(s) or component(s) when the proportion of such ingredient(s) or component(s) in the food has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present in an amount greater than is actually the case. The following requirements shall apply unless modified by a specific regulation in subpart B of this part.

(1) The percentage of a characterizing ingredient or component shall be declared on the basis of its quantity in the finished product (i.e., weight/weight in the case of solids, or volume/volume in the case of liquids).

(2) The percentage of a characterizing ingredient or component shall be declared by the words "containing (or contains) ___ percent (or %) ___ " or "___ percent (or %) ___" with the first blank filled in

with the percentage expressed as a whole number not greater than the actual percentage of the ingredient or component named and the second blank filled in with the common or usual name of the ingredient or component. The word "containing" (or "contains"), when used, shall appear on a line immediately below the part of the common or usual name of the food required by paragraph (a) of this section. For each characterizing ingredient or component, the words "___ percent or %) ___" shall appear following or directly below the word "containing" (or contains), or directly below the part of the common or usual name of the food required by paragraph (a) of this section when the word "containing" (or contains) is not used, in easily legible boldface print or type in distinct contrast to other printed or graphic matter, and in a height not less than the larger of the following alternatives:

(i) Not less than one-sixteenth inch in height on packages having a principal display panel with an area of 5 square inches or less and not less than one-eighth inch in height if the area of the principal display panel is greater than 5 square inches; or

(ii) Not less than one-half the height of the largest type appearing in the part of the common or usual name of the food required by paragraph (a) of this section.

* * * * *

11. 21 C.F.R. § 102.33 provides in pertinent part:

Beverages that contain fruit or vegetable juice.

(a) For a carbonated or noncarbonated beverage that contains less than 100 percent and more than 0 percent fruit or vegetable juice, the common or usual

name shall be a descriptive name that meets the requirements of § 102.5(a) and, if the common or usual name uses the word "juice," shall include a qualifying term such as "beverage," "cocktail," or "drink" appropriate to advise the consumer that the product is less than 100 percent juice (e.g., "diluted grape juice beverage" or "grape juice drink").

(b) If the product is a diluted multiple-juice beverage or blend of single-strength juices and names, other than in the ingredient statement, more than one juice, then the names of those juices, except in the ingredient statement, must be in descending order of predominance by volume unless the name specifically shows that the juice with the represented flavor is used as a flavor (e.g., raspberry-flavored apple and pear juice drink). In accordance with § 101.22(i)(1)(iii) of this chapter, the presence of added natural flavors is not required to be declared in the name of the beverage unless the declared juices alone do not characterize the product before the addition of the added flavors.

(c) If a diluted multiple-juice beverage or blend of single-strength juices contains a juice that is named or implied on the label or labeling other than in the ingredient statement (represented juice), and also contains a juice other than the named or implied juice (nonrepresented juice), then the common or usual name for the product shall indicate that the represented juice is not the only juice present (e.g., "Apple blend; apple juice in a blend of two other fruit juices.")

(d) In a diluted multiple-juice beverage or blend of single-strength juices where one or more, but not all, of the juices are named on the label other than in the ingredient statement, and where the named juice is

not the predominant juice, the common or usual name for the product shall:

(1) Indicate that the named juice is present as a flavor or flavoring (e.g., "Raspcranberry"; raspberry and cranberry flavored juice drink); or

(2) Include the amount of the named juice, declared in a 5-percent range (e.g., Raspcranberry; raspberry and cranberry juice beverage, 10- to 15-percent cranberry juice and 3- to 8-percent raspberry juice). The 5-percent range, when used, shall be declared in the manner set forth in § 102.5(b)(2).

(e) The common or usual name of a juice that has been modified shall include a description of the exact nature of the modification (e.g., "acid-reduced cranberry juice," "deflavored, decolored grape juice").

* * * * *

(g)(1) If one or more juices in a juice beverage is made from concentrate, the name of the juice must include a term indicating that fact, such as "from concentrate," or "reconstituted." Such terms must be included in the name of each individual juice or it may be stated once adjacent to the product name so that it applies to all the juices, (e.g., "cherry juice (from concentrate) in a blend of two other juices" or "cherry juice in a blend of 2 other juices (from concentrate)"). The term shall be in a type size no less than one-half the height of the letters in the name of the juice.

* * * * *

REPLY BRIEF

Supreme Court, U.S.
FILED
APR 11 2014
OFFICE OF THE CLERK

No. 12-761

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RULE 29.6 STATEMENT

The Rule 29.6 statement included in Pom Wonderful LLC's opening brief remains correct.

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ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

REPLY BRIEF FOR PETITIONER

Because Pom's Lanham Act claim was dismissed as a matter of law, this case comes to the Court on a limited record. But the complaint and record evidence show that Coca-Cola is willfully misleading consumers in order to take market share from Pom. Coca-Cola sells and markets as "POMEGRANATE BLUEBERRY" a product that contains only 0.3% pomegranate juice and 0.2% blueberry juice. There is no way consumers can know that Coca-Cola's product contains almost no pomegranate or blueberry juice, and consumers are, in fact, misled—a risk Coca-Cola was "willing to assume." Pet. App. 32a-35a.

Against this backdrop, Coca-Cola urges the Court to deny Pom the remedy Congress expressly provided businesses against competitors who misappropriate market share by intentionally misleading consumers about the product they sell. But Coca-Cola provides no colorable support for that extraordinary request. It concedes that no provision of the Food, Drug and Cosmetic Act ("FDCA") or the Nutrition Labeling and Education Act of 1990 ("NLEA") expressly displaces the Lanham Act. And it does not even attempt to show that the Lanham Act irreconcilably conflicts with the FDCA or the NLEA.

Instead, Coca-Cola asks this Court to divine an unspoken congressional intent in the NLEA to displace the Lanham Act in order to achieve "national uniformity"—a phrase Coca-Cola recites scores of times. The substantive provisions of the NLEA, however, established rules governing nutritional information and health claims on food labeling, which are not at issue here. Thus, all Coca-Cola can point to is the NLEA's express preemption clause, which displaces only state law—not federal law—and even then does so only partially. The fact that Congress preempted some state laws governing food labeling but did not displace the Lanham Act bolsters the case *against* preclusion. It is a non sequitur to argue, as Coca-Cola does, that a federal interest in uniformity compels the conclusion that Congress, without saying so, intended to limit application of the *nationally uniform federal* Lanham Act. Application of that law by judges and juries on a case-by-case basis is no more at odds with uniformity than application of the federal securities laws, the Patent Act, or any other federal law.

The United States agrees that the judgment should be reversed, and it correctly urges the Court to permit

Pom's challenge to Coca-Cola's label as a whole to proceed. But the United States errs in contending that the *name* of Coca-Cola's product is immune from challenge if it is in compliance with FDA's juice-naming regulation (a question the United States recognizes cannot be resolved on the limited, existing factual record). That position cannot be reconciled with *Wyeth* v. *Levine*. Even more so than the drug-labeling regime at issue in *Wyeth*, which required FDA to approve the specific label later challenged in state-court litigation, FDA's juice regulations do not set a "ceiling." A company may avoid FDA enforcement action to the extent it complies with FDA's rules, but that does not confer immunity for misleading consumers and unfairly acquiring market share. Nothing in the regulations prevented Coca-Cola from using a label (and a name) that would not mislead consumers. Coca-Cola chose a markedly different path, and it is responsible for defending that choice under the Lanham Act.

I. THE LANHAM ACT CANNOT BE SET ASIDE ABSENT AN IRRECONCILABLE CONFLICT

Coca-Cola argues (18-21) that a subsequently enacted "specific" federal law can nullify a more "general" law even in the absence of an irreconcilable conflict. It thus contends (21-22) that the Lanham Act can be rendered inapplicable if the Court is able to discern an unarticulated congressional intent to do so in the 1990 NLEA. Coca-Cola's invitation to re-write the Lanham Act in the guise of clarifying it should be rejected.

As the Solicitor General points out (3 n.2, 17), the substantive statutory provisions at issue derive from the 1938 FDCA—not from the NLEA, which added provisions directed to *nutritional* information not at issue in this case. *See infra* pp. 10-11. The only NLEA

provision remotely relevant is a partial *state-law* preemption provision that by its terms does not apply to Pom's Lanham Act claim. *See infra* pp. 7-14. This alone disposes of Coca-Cola's contention that the NLEA implicitly narrows the scope of the Lanham Act.

Moreover, the "general/specific" canon applies only where "a general permission or prohibition is contradicted by a specific prohibition or permission" or where the specific provision would be rendered superfluous by the general one. *RadLAX Gateway Hotel, LLC* v. *Amalgamated Bank*, 132 S. Ct. 2065, 2071 (2012). There is no "contradict[ion]" or "superflu[ity]" here. *Id.* The FDCA "prohibit[s]" misbranding, 21 U.S.C. §§331, 343, and subjects violators to criminal and regulatory penalties, *id.* §§333(a), 334(a)(1). The Lanham Act bars "false or misleading" statements in commercial advertising and provides civil remedies to injured competitors. 15 U.S.C. §§1125(a)(1), 1117-1118. No one disputes that compliance with both prohibitions is possible.

The cases Coca-Cola relies on (18-20) do not support its position. The very passage Coca-Cola quotes from *United States* v. *Fausto*, 484 U.S. 439 (1988), underscores the important difference between implying preclusion of "express statutory text" (*id.* at 453)—which is exactly what Coca-Cola advocates here—and reading a subsequent statute, enacted to "comprehensively overhaul[]" (*id.* at 443) an "outdated patchwork of ... rules" (*id.* at 444), sensibly to reject "the implication" of a remedy under the *ancien regime* (*id.* at 453). *See also id.* ("All that we find to have been 'repealed' by the CSRA is the judicial interpretation of the Back Pay Act"). When the former is at stake, as here, *Fausto* reaffirms that "it can be strongly presumed that Congress will specifically address language on the statute books that it wishes to change." *Id.*

Elgin v. *Department of Treasury*, 132 S. Ct. 2126, 2133 (2012), is even more inapposite. It falls under this Court's precedents addressing laws that "simply channel[] judicial review of a constitutional claim to a particular court." *Id.* at 2132. In such cases, the only question is whether the same claim can be brought in multiple fora. In answering that question, the Court understandably does not require Congress to recite the obvious: that it intends to avoid "duplicative judicial review." *Id.* at 2135, 2133-2136.

Coca-Cola also invokes *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000), and *Dastar Corp.* v. *Twentieth Century Fox Film Corp.*, 539 U.S. 23 (2003), for the principle that, where a statute has a "range of plausible meanings" when enacted, "subsequent acts can shape or focus *those* meanings." Resp. Br. 20 (quoting *Brown & Williamson*, 529 U.S. at 143) (emphasis added). Neither of those cases (or the other two Coca-Cola cites)[1] creates a judicial license to venture outside a statute's "range of plausible meanings" absent an irreconcilable conflict. *Brown & Williamson*, 529 U.S. at 143.

Here, Coca-Cola struggles even to articulate which language in the Lanham Act it purports to interpret.

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[1] In *United States* v. *Estate of Romani*, the Court found a "'plain inconsistency'" between the two relevant statutes. 523 U.S. 517, 533 (1998). In *Brotherhood of Railroad Trainmen* v. *Chicago River & Indiana Railroad Co.*, the Court held that the plain terms of the Railway Labor Act ("RLA") "should be literally applied in the absence of a clear showing of a contrary or qualified intention of Congress." 353 U.S. 30, 35 (1957); *see also id.* at 41 ("'[T]he Norris-LaGuardia Act can affect the present decree only so far as its provisions are found not to conflict with those of [the RLA]....'").

In a footnote (20-21 n.10), Coca-Cola contends that the Lanham Act's phrase "false or misleading" should be construed to mean false or misleading unless the deception involves "aspects of a nationally-uniform juice label that have been chosen in compliance with the FDCA and the FDA's regulations." That is not *interpretation* of statutory text; it is statutory *revision* that must be rejected absent an irreconcilable conflict.

II. Under Any Framework, The NLEA And The FDCA Do Not Displace The Lanham Act

In any event, under any framework, Coca-Coca's argument that the NLEA and the FDCA *sub silentio* displace the Lanham Act fails. There is no indication Congress intended such displacement.

A. There Is No Irreconcilable Conflict

Coca-Cola does not contest that it "can easily satisfy both [statutory] mandates." *Department of Transp.* v. *Public Citizen*, 541 U.S. 752, 767 (2004). It claims (48) that the Lanham Act and the FDCA are in "tension" because they both apply to the "same thing" in "non-identical" ways. But this "tension" merely reflects the statutes' distinct purposes. "[A] typical false-advertising case ... implicate[s] *only* the [Lanham] Act's goal of 'protect[ing] persons engaged in [commerce within the control of Congress] against unfair competition'"—not consumer protection. *Lexmark Int'l, Inc.* v. *Static Control Components, Inc.*, 572 U.S. __ (2014) (slip op. 12) (last alteration in original; emphasis added). In contrast, the FDCA's misbranding provisions protect the public's health and safety through

criminal and regulatory penalties. Pet. Br. 26-27; 21 U.S.C. §393 (b)(2)(A).[2] In any event, "tension" does not establish an "irreconcilable conflict." *Public Citizen*, 541 U.S. at 766-767.[3]

B. The NLEA's Preemption Provision Does Not Support Coca-Cola

Coca-Cola's position (16, 24-36) rests almost entirely on the argument that the NLEA's state-law preemption provision sought to achieve "national uniformity" and thus shows that Congress must have also "intended to preclude a Lanham Act claim." There is no support for that novel contention, which disregards the NLEA's

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[2] Coca-Cola suggests (4, 48) that the FDCA provisions at issue are a form of economic consumer protection, but the provision Coca-Cola cites (21 U.S.C. §341) is irrelevant to the issues in this case.

[3] In a footnote (21-22 n.11), Coca-Cola cites *Credit Suisse Securities (USA) LLC* v. *Billing*, 551 U.S. 264 (2007), which applied the unique doctrine of antitrust immunity. *See, e.g., Branch* v. *Smith*, 538 U.S. 254, 293 (2003) (O'Connor, J., concurring in part) ("[O]utside the antitrust context, we appear not to have found an implied repeal of a statute since 1917."). But here, Pom's claim poses *no* risk of a "'chilling effect' on 'lawful joint activities ... of tremendous importance to the economy of the country.'" 551 U.S. at 283. Quite the contrary, FDA has "*encouraged*" manufacturers to declare "each juice in a beverage ... in the name of the product." 58 Fed. Reg. 2897, 2919 (Jan. 6, 1993) (emphasis added). Further, unlike the SEC in *Credit Suisse*, FDA has not "actively enforce[d] the rules and regulations that forb[ade] the conduct in question." *Compare* 551 U.S. at 283, *with* Pet. Br. 52-56; *infra* pp. 22-23. And FDA has no statutory obligation to address the concerns underpinning the purportedly conflicting statute. *Compare* 551 U.S. at 283, *with* U.S. Pet. Br. 14 (FDA lacks "authority to resolve a competitor's claim of competitive injury due to a misleading label.").

text, misconstrues its purpose, lacks foundation in this Court's precedents, and fails even on its own terms.

1. When Congress wants to preclude both state and federal law, it does so explicitly—including in the context of product labeling. *See, e.g.*, 15 U.S.C. §1334(a) ("[N]o statement relating to smoking and health, other than the statement required by [15 U.S.C. §1333], shall be required on any cigarette package."); *cf.* 49 U.S.C. §10501 ("[R]emedies provided under [Surface Transportation Board statute] are exclusive and preempt the remedies provided under Federal or State law."). In §343-1, Congress did the opposite: It expressly preempted only certain state requirements, disavowed any implied preemption, and never mentioned federal law.

Coca-Cola questions (31-32 & n.20) whether Congress was really aware that the Lanham Act applied to misleading food labels. But this Court presumes Congress' knowledge of the law, *see Cannon* v. *University of Chi.*, 441 U.S. 677, 697-698 (1979), and the decisions and hearings cited by Pom (29-30) underscore that there is no basis to discard that presumption here. The pendency of Lanham Act suits against misleading juice labels just as Congress was considering the NLEA confirms as much. *See, e.g., Grove Fresh Distribs., Inc.* v. *Flavor Fresh Foods, Inc.*, 720 F. Supp. 714, 715 (N.D. Ill. 1989) ("Flavor Fresh 100% Orange Juice from Concentrate").

2. Nor can Coca-Cola justify its atextual interpretation based on an asserted need for "national uniformity." As Pom previously explained (31), laws that prohibit false or misleading labeling do apply a "'single, uniform'" standard. *Altria Group, Inc.* v. *Good*, 555 U.S. 70, 79-80 (2008); *see also id.* at 82. That is true, a

fortiori, where the relevant standard is set out in a *federal* statute. Congress has long recognized private rights of action under federal laws even in areas where the need for national uniformity has constitutional pedigree. *See Bonito Boats, Inc.* v. *Thunder Craft Boats, Inc.*, 489 U.S. 141, 162 (1989) ("[O]ne of the fundamental purposes behind the Patent ... Clause[] ... was to promote national uniformity in the realm of intellectual property."); 35 U.S.C. §281 (private right of action for patent infringement).

Coca-Cola's and its amici's concern with inconsistent jury determinations is similarly unfounded. *See* Resp. Br. 2, 25, 29; GPhA Br. 12; Am. Bev. Ass'n Br. 6, 15; Chamber of Commerce et al. Br. 27. The FDCA specifically "contemplates that federal juries will resolve most misbranding claims." *Wyeth* v. *Levine*, 555 U.S. 555, 570 (2009). "[L]ay juries," therefore, "are in no sense anathema to [the FDCA's] scheme." *Bates* v. *Dow AgroSciences LLC*, 544 U.S. 431, 452 (2005) ("[T]here is no reason to think [inconsistent verdicts] would be frequent or that they would result in difficulties beyond those regularly experienced by manufacturers of other products that every day bear the risk of conflicting jury verdicts."). Nor can Coca-Cola or its amici point to a single instance of such inconsistent determinations, despite the longstanding availability of Lanham Act claims in this area. *See* Pet. Br. 29.[4] This

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[4] Fearmongering by Coca-Cola and its amici that one jury will require one thing and another will mandate something different is no more persuasive here than it was in *Wyeth*. Juries do not prescribe the contents of labels: They decide only whether, on the evidence presented, a challenged label is false or misleading and, if so, whether the manufacturer acted willfully.

case confirms that juice manufacturers—like all other participants in the national economy, who are undisputedly subject to the Lanham Act—can readily ascertain when their products pose a "'risk from a misleading standpoint.'" Pet. App. 35a.

The structure of §343-1 squarely refutes Coca-Cola's argument that Congress intended absolute "national uniformity." Certain FDCA misbranding requirements *never* preempt state laws—most significantly, the FDCA's prohibition on false or misleading labels, §343(a)(1). Resp. Br. 33, 52; U.S. Br. 25. States, moreover, can petition for exemptions from preemption (§343-1(b)), and may directly enforce certain misbranding provisions when FDA does not (§337(b)). And courts and juries necessarily interpret the FDCA and FDA regulations when adjudicating state-law claims that are "identical" to the FDCA and thus not preempted. *See* 21 U.S.C. §343-1(a)(1)-(5); U.S. Br. 27.[5] The NLEA thus reflects a compromise between even *state-by-state* regulation and "national uniformity"—not complete abdication to FDA.

To the extent the NLEA expresses any heightened desire for uniformity, it is with respect to nutritional information. Congress's purpose in enacting the *Nutrition* Labeling and Education Act was "to make sense of the confusing array of nutrition labels" then prevailing. 136 Cong. Rec. H5840 (July 30, 1990) (Rep. Waxman). To accomplish this goal, the NLEA required "[n]utrition [l]abeling" in most food products—i.e., the

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[5] Coca-Cola takes the extreme position (33 n.23) that even claims under "identical" state laws cannot proceed. That contention is foreclosed by the plain terms of §343-1.

now-ubiquitous "Nutrition Facts" panel. *See* Pub. L. No. 101-535, §2, 104 Stat. 2353 (21 U.S.C. §343(q) ("Nutrition Labeling")). NLEA thus created a "uniform nutrition label that would disclose the amount of calories, fat, salt, and other nutrients." 136 Cong. Rec. at H5840.[6] Indeed, the section title upon which Coca-Cola so heavily relies (1, 7, 24, 51 n.40) refers to "National Uniform *Nutrition* Labeling." 21 U.S.C. §343-1 (emphasis added).

3. There is also no support in this Court's precedents for Coca-Cola's contention that NLEA's selective preemption of state law can be extended to preclude claims under federal law. Coca-Cola cites *Fausto* and *Elgin* (24), but those cases—both of which arise in the context of the Civil Service Reform Act and neither of which involves a preemption provision—are wholly inapposite. The "leading purpose" of the statute was "to replace the haphazard arrangements for administrative and judicial review of personnel action" for federal employees, *Fausto*, 484 U.S. at 444, with a comprehensive, integrated system of review that would remove the risk of inconsistent "fact-finding as well as interpretation of law" by different courts with concurrent jurisdiction, *id.* at 451. *See Elgin*, 132 S. Ct. at 2135 (similar). In contrast, nothing in the NLEA suggests that

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[6] *See also id.* at H5843 ("The main features of the bill require mandatory nutrition labeling for most foods that will be uniform throughout the country.") (Sen. Madigan); 136 Cong. Rec. S16607, S16609 (Oct. 24, 1990) ("The elements of this bill will help all consumers to better understand and improve their eating habits by providing uniform nutritional information in a coherent and understandable format.") (Sen. Mitchell); *id.* at S16610 (NLEA "will mandate that all processed package foods have uniform nutritional labels") (Sen. Hatch).

Congress was interested in concentrating adjudications in any particular forum. The NLEA left district courts in charge of resolving charges of misbranding, continued to permit parallel state-court proceedings under state law, and actually created a vehicle for state authorities to bring their own FDCA enforcement proceedings (presumably in state courts) when FDA does not. Pub. L. No. 101-535, §4, 104 Stat. 2353 (21 U.S.C. §337(b)).[7] The NLEA was intended only to avoid state-by-state variations in substantive standards. That interest is not implicated by permitting enforcement of a federal statute that applies equally in all 50 States.

Coca-Cola also cites (25-26) three lower-court decisions addressing the interplay between the Federal Employers' Liability Act ("FELA"), which provides a negligence remedy for railroad employees, and the Federal Railroad Safety Act ("FRSA"), which requires the Secretary of Transportation to promulgate standards for the safe operation of railroads that expressly preempt state law. The cited cases, which represent one side of a developing split,[8] lack analogic force. Pre-

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[7] *Keogh* v. *Chicago & Northwestern Railway Co.*, 260 U.S. 156 (1922), is even farther afield. *Keogh* held that the filed-tariff doctrine precluded damages under the Sherman Act because such damages "might, like a rebate, operate to give ... a preference [to the plaintiff] over his trade competitors." *Id.* at 163. Nothing of the sort is at issue here.

[8] *See, e.g.*, *Cowden* v. *BNSF Ry. Co.*, 690 F.3d 884, 892 (8th Cir. 2012) (deciding appeal on other grounds to avoid "creat[ing] a circuit split on this issue"); *Infermo* v. *New Jersey Transit Rail Operations, Inc.*, No. 10-2498, 2012 WL 209359, at *6 (D.N.J. Jan. 24, 2012) (preclusion of FELA "very problematic"); *Earwood* v. *Norfolk S. Ry. Co.*, 845 F. Supp. 880, 891 (N.D. Ga. 1993) (rejecting FELA preclusion).

clusion of FELA claims might be justified by the need to avoid disparate treatment of accident victims who differ only with respect to their status as railroad employees or non-employees. *See Lane* v. *R.A. Sims, Jr., Inc.*, 241 F.3d 439, 442 (5th Cir. 2001). By contrast, here, *all* plaintiffs suffering an "injury to a commercial interest" are able to sue. *Lexmark* (slip op. at 13). Any "disparity" between commercial plaintiffs (who have a federal remedy under the Lanham Act) and consumers (who have rights under state law) would merely reflect Congress' judgment that commercial plaintiffs suffer different types of harm. *See id.*

4. Even assuming §343-1 could somehow affect other federal laws, Pom's Lanham Act claim would still proceed. Coca-Cola strives (28-29) to link each allegation underlying Pom's claim to a subsection of §343. But if Pom's Lanham Act challenge is "of the type" of any section of the FDCA, it would be §343(a)(1)—the FDCA's prohibition on misleading labeling. *Cf. Altria*, 555 U.S. at 84 (prohibition on deceptive practices "is a general rule that creates a duty not to deceive" and is not "'based on'" the specific subject matter addressed by the preempting provision). State-law claims that parallel §343(a)(1) are not preempted under the NLEA. *See* 21 U.SC. § 343-1 & note (saving clause).[9]

Coca-Cola's only response (32) is that Congress "cannot have contemplated" that §343(a)(1) would

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[9] Several courts have found that state-law claims challenging labels as misleading are not preempted. *See, e.g., Chavez* v. *Blue Sky Natural Beverage Co.*, 268 F.R.D. 365, 370 (N.D. Cal. 2010); *Pom Wonderful LLC* v. *Ocean Spray Cranberries, Inc.*, 642 F. Supp. 2d 1112, 1122 (C.D. Cal. 2009). The district court in this case disagreed, but Pom's appeal is pending.

"cover" circumstances where other §343 subsections might also be relevant. But, again, Coca-Cola is asking the Court to imagine carve-outs in the statutory text (this time, in §343) that Congress never enacted. In fact, Coca-Cola acknowledges (33 n.22) that FDA has used §343(a)(1) precisely to address misleading labels "covered" in part by other subsections of §343.[10] *See* U.S. Br. 19 (compliance with specific FDA regulations does not make label non-misleading).

C. FDA's Juice-Naming Regulations Do Not Displace The Lanham Act

Coca-Cola and the government argue that FDA's regulations displace the Lanham Act where they specifically "permit" the challenged aspects of a label. This argument fails in multiple respects.

As a threshold matter, the government's analysis of the juice-naming regulations (18-20) relies on "obstacle" preemption cases. The "irreconcilable conflict" standard, however, is markedly more demanding—courts must strive, wherever possible, to give full effect to all congressional enactments. *See* Pet. Br. 20-21. Moreover, while federal regulations can preempt state laws, federal regulations cannot trump a federal statute. Thus, whatever may be said about "obstacle" preemption, *see Wyeth*, 555 U.S. at 594 (Thomas, J., concurring in the judgment), analogies to that doctrine here are a

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[10] *See also* Institute of Medicine, *Food Labeling: Toward National Uniformity* 77 (1992) (noting "interrelationship" of § 343(a)(1) with other subsections and that, "when the Committee reviewed the enforcement history of regulatory actions taken by FDA, it invariably encountered charges under multiple sections of FDCA").

one-way street: They can (and, in this case, do) prove that a federal statute is not impliedly precluded, but not vice versa.

In any event, the government's preemption analysis is flawed. As in *Wyeth*, FDA's juice-labeling regulations constitute merely a "floor," not a "ceiling." The government attempts (20) to distinguish *Wyeth*, but the purported distinctions it draws bolster the case *against* preclusion. The government first notes the absence of an express state-law preemption provision in *Wyeth*. But the government elsewhere acknowledges (25 n.10) that "[t]here is ... little reason to think Congress intended to preclude federal Lanham Act claims to the same extent state-law claims are expressly preempted." The government also notes that *Wyeth* relied in part on statements previously made by FDA disclaiming preemption. But the Court relied on those statements to reject FDA's "dramatic change in position." 555 US. at 579. Finally, the government observes that, in *Wyeth*, FDA had not "consider[ed] and reject[ed] a stronger warning." Here, however, FDA has never reviewed Coca-Cola's label much less rejected any proposal to make that label less misleading. *See* U.S. Br. 29 n.12.

Fidelity Federal Savings & Loan Ass'n v. *de la Cuesta*, 458 U.S. 141 (1982), which did not involve displacement of a federal statute, highlights why FDA's juice-naming regulation is a particularly poor candidate for implied preclusion. In *de la Cuesta*, the Court found preemption because there was a clear conflict between an agency's affirmative grant of "power" to the regulated entities and a state law restricting that "power." *Id.* at 141, 146-147, 154. In contrast, the FDCA's food misbranding provisions (and, thus, FDA's regulations) do not authorize conduct. They establish what the FDCA forbids manufacturers from doing lest their

products be considered misbranded and they be subject to government enforcement. *See* 21 U.S.C. §331(a) ("prohibit[ing]" misbranding); *id.* §343 (giving content to "misbranding").

Geier v. *American Honda Motor Co.*, 529 U.S. 861 (2000), is likewise inapposite. *Geier* holds that where an agency acts to *encourage* the conduct being challenged in order to advance the statute's regulatory purpose, state laws cannot undermine that judgment. *Id.* at 881. But here, FDA has not encouraged manufacturers to obscure the contents of their products as Coca-Cola has done. FDA has "*encouraged*" manufacturers to declare "each juice in a beverage ... in the name of the product." 58 Fed. Reg. 2897, 2919 (Jan. 6, 1993). The government hints (19) at an undefined interest in manufacturer "'flexibility'" in this case. The Court, however, has rejected flexibility for flexibility's sake as a "significant regulatory objective" entitled to preemptive effect. *Williamson* v. *Mazda Motor of Am.*, 131 S. Ct. 1131, 1137 (2011). "[T]o infer from the mere existence of ... cost-effectiveness judgment that the federal agency intends to bar States from imposing stricter standards would treat all ... federal standards as if they were *maximum* standards." *Id.* at 1139.

D. Section 337 Does Not Displace The Lanham Act

There is no support for Coca-Cola's contention (23, 33 n.23, 39 n.29) that §337(a) precludes Lanham Act claims for misleading juice labels. Section 337(a) makes the government the exclusive enforcer of the FDCA, not the Lanham Act. Nor can Coca-Cola's argument be reconciled with *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 494-497 (1996), and *Riegel* v. *Medtronic, Inc.*, 552 U.S. 312, 330 (2008), where the Court allowed state-law

claims "parallel" to the FDCA's provisions to proceed. *Cf. Bates*, 544 U.S. at 447-448 (FIFRA); *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341, 352-353 (2001) (distinguishing state-law claims in *Lohr* because they did not arise "solely from the violation of FDCA requirements").

III. COCA-COLA'S MISLEADING LABEL DOES NOT COMPLY WITH THE FDCA AND FDA'S REGULATIONS

For the foregoing reasons, Pom's Lanham Act claim should be allowed to proceed regardless of Coca-Cola's alleged regulatory compliance. Pom's challenge does not depend on the FDCA or FDA's regulations; it is Coca-Cola's theory that would "inject[] FDCA compliance questions into the case." U.S. Br. 28; *see* JA53a ("Thirty-Second Affirmative Defense."). In any event, Coca-Cola's compliance theory is deeply flawed.

Label as a Whole. No FDA regulation forecloses Pom's challenge to Coca-Cola's label as a whole. The government recognizes (19) that compliance with FDA's juice-naming regulation does not "render a juice *label* non-misleading" (emphasis added). Pom is thus entitled to proceed with its challenge to Coca-Cola's product and have a jury decide whether the label in its totality—including the name—is misleading. That is precisely the approach FDA took in the 2009 Warning Letter cited in Pom's opening brief (37 & n.6). In deeming the juice labels "misleading" under §343(a)(1), FDA relied principally on the juice names:

> The principal display panels identify the products as "Orange Tangerine" and "Grape," respectively, in large, bold lettering outlined in black; however, neither orange/tangerine juice

> nor grape juice is the predominant juice in the products.[11]

It noted other factors only as subsidiary considerations. *Id.* Just as FDA's finding of deception in that case was not "based on" the juice names, U.S. Br. 19 n.7, so too Pom would be permitted to argue to the jury, among other things, that Coca-Cola's label is misleading for displaying the words "Pomegranate Blueberry" in "large, bold lettering."

Font Sizes. Coca-Cola's new contentions that certain FDA regulations bar Pom from challenging the misleading use of a diminutive font for the words "Flavored Blend Of 5 Juices" are meritless. In the court of appeals, Coca-Cola relied only on §343(f) and §101.2 and §101.3 of FDA's regulations. *See* Appellees Br. 16. In its supplemental brief opposing certiorari, Coca-Cola claimed (3) for the first time that an FDA regulation requiring disclosure of added flavorings, §101.22(i)(1)(i), authorizes its reduced font size for the words "Flavored Blend of 5 Juices." FDA not only disagrees with the applicability of that regulation, *see* U.S. Br. 31-32, but also has explained that the provision does not address the font size of the phrase "Blend Of 5 Juices," *id.* 33.

Coca-Cola now claims (44 n.33) that a different provision, §101.22(i)(1)(iii), excuses its font-size selection. But that provision governs only the phrase "With Other Natural Flavor." 21 C.F.R. §101.22(i)(1)(iii) ("the name of the food shall be immediately followed by the

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[11] Warning Letter from Roberta F. Wagner, FDA, to Brad Alford, Nestle U.S.A., Dec. 4, 2009, *available at* http://www.fda.gov/iceci/enforcementactions/warningletters/ucm194122.htm.

words 'with other natural flavor' in letters not less than" the font size of the juice's name); U.S. Br. 32 n.15.

The Product Name. Coca-Cola's admission (44 n.33) that §101.22(i)(1)(iii) "directly applies here" confirms that Coca-Cola's product name is not in compliance. Section 101.22(i)(1)(iii) requires that "the name of the food shall be *immediately followed* by the words 'with other natural flavor.'" (Emphasis added.) Attempting to satisfy this requirement, Coca-Cola now proclaims (44 n.33) for the very first time in this litigation (and likely ever) that the name of its product is actually, improbably, "POMEGRANATE BLUEBERRY FLAVORED BLEND OF 5 JUICES FROM CONCENTRATE WITH ADDED INGREDIENTS." But that dubious contention cannot be squared with the label itself, Coca-Cola's prior assertions, or the regulations Coca-Cola invokes. *See* Br. in Opp. 4; Appellee Br. 17; 21 C.F.R. §102.33(g)(1) (if stated just once, "from concentrate" must be "adjacent to the product name"); §101.30(b)(3) (not a naming regulation).

Additionally, as Pom has explained (51-52), a separate FDA regulation, §102.5(b), mandates declaration of the percent content of ingredients when the information "has a material bearing on price or consumer acceptance" or its omission would "create an erroneous impression." Coca-Cola does not contest that the pomegranate and blueberry juices meet §102.5(b)'s definition. Coca-Cola merely contends (38 n.28) that §102.5(b) does not apply because it has been "'modified by a specific regulation.'" But the text of §102.5(b) makes crystal clear that only its technical presentation requirements set forth at §102.5(b)(1)-(2) may be so modified. *See* 21 C.F.R. §102.5(b) (stating *after setting forth the percent-declaration* requirement: "The *following* requirements

shall apply unless modified by a specific regulation in subpart B of this part" (emphasis added)).

Finally, FDA has now concluded that to determine compliance with §102.33(d)(1), a remand would be necessary to adjudicate an "unresolved factual dispute": whether pomegranate and blueberry juices are, in fact, "'present as ... flavor[s] or flavoring[s]'" as required. U.S. Br. 22-23 & n.8. Coca-Cola argues (40-41) that a juice can be present "as a flavor" even though it is present only in trivial amounts that must be "reinforced by added flavors." But that position, which would allow mere microns of a juice to satisfy §102.33(d)(1), is contradicted by both the plain meaning of the word "flavor" and FDA's longstanding position."[12] This issue was by no means waived. Coca-Cola's non-compliance came to light only when Coca-Cola admitted to it by invoking §101.22(i)(1)(i) in its supplemental brief. Resp. Supp. Br. 3; Pet. Br. 49-50. Because Pom's challenge was dismissed at the pleading stage, Pet. App. 92a, Pom has not had the opportunity to develop an adequate record.

Vignette, Multiple Lines, and Color. As the government explains, "nothing in the FDCA or its implementing regulations precludes" a claim against Coca-Cola's "fruit vignette as misleading." U.S. Br. 30 n.14; *see also id.* (after considering whether to issue specific regulations, FDA "ultimately opted for a case-by-case assessment" of vignettes); 58 Fed. Reg. at 2922 (same).

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[12] *See* 58 Fed. Reg. at 2921 ("[T]he term 'flavor' with the name of the characterizing juice will inform the consumer that *the juice is present in an amount sufficient to flavor the beverage.*" (emphasis added)); U.S. Br. 23. The FDA discussion of flavored *waters* (58 Fed. Reg. at 2921) Coca-Cola cites (40) is inapposite.

Coca-Cola would infer from FDA's approach a license to use misleading vignettes until FDA takes action. But FDA itself (30 n.14) has rejected that interpretation in this case. Nor do any FDA regulations address Coca-Cola's decision to divide its product's name into different lines, or color its juice, in a misleading manner.

Again, Coca-Cola resorts to arguing waiver (28 n.16, 38-49). But at every stage, Pom has challenged Coca-Cola's label *as a whole*, and it has specifically identified individually misleading aspects of Coca-Cola's label.[13] And, at every juncture, Coca-Cola has attempted to respond.[14] The Ninth Circuit acknowledged that Pom challenged Coca-Cola's "name, labeling, marketing, and advertising." Pet. App. 3a. It addressed both "Pom's challenge to the name" and "the labeling component of Pom's claim." *Id.* 9a-10a. Although the court incorrectly stated that Pom did not "meaningfully" challenge the label's vignette on appeal, *id.* 10a,[15] the court did *not* find that Pom waived that

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[13] *See, e.g.*, Appellant Br. 1 ("Coca-Cola's naming and labeling"); *id.* n.1 (font size and line breaks); *id.* 28 n.11 (label's "place[ment of] 'Pomegranate Blueberry' on a separate line and in a larger font" and Coca-Cola's misleading "fruit vignette"); Pet. for Reh'g and Reh'g En Banc 3 (listing "several factors [that] worked together to create th[e] misleading effect, including the juice's name and font size, the fruit vignette on the juice's front label ..., and the juice's dark purple color").

[14] *See, e.g.*, Appellee Br. 5 (juice-naming and vignette); *id.* 16 (font size and line breaks); *id.* 24 (name and vignette); *id.* 43 ("Pom contends that the Juice's label violates the [FDCA]'s *general misbranding provisions*—and by extension, the Lanham Act." (emphasis added)).

[15] *See* Appellant Br. 28 n.11 ("[N]o FDA regulation mandated that Coca-Cola place the words 'Pomegranate Blueberry' on a sep-

argument. When the Ninth Circuit declares an argument waived, it does so explicitly. *E.g.*, *Cruz* v. *International Collection Corp.*, 673 F.3d 991, 998 (9th Cir. 2012).[16] To the extent the vignette, line breaks, and coloring have been discussed by the parties in less detail than other aspects of the label, that is a function of the way in which Coca-Cola has raised its alleged regulatory-compliance defense.

IV. Coca-Cola's Position Would Have Far-Reaching And Unintended Consequences

FDA does not contest that it utterly lacks the resources to engage in meaningful oversight of food labels. *See* Pet. Br. 52-54. Coca-Cola demurs, relying (49-50) on FDA's 1993 certification that certain FDCA provisions were "adequately implemented." But in making that determination, FDA considered neither "the level of FDA enforcement" nor "the level of industry compliance." 58 Fed. Reg. 2470, 2471 (Jan. 6, 1993). FDA's certification thus says nothing about the agency's ability—or, more accurately, inability—to police false and misleading food labeling. The few warning letters issued by FDA in the context of food labeling cited by Coca-Cola and its amici pertain almost entirely to *nutrition* labeling and health claims. *See* Friedman

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arate line and in a larger font than the words 'Flavored Blend of 5 Juices' or use a fruit vignette on its label that features a disproportionately large pomegranate.").

[16] If anything was waived, it is Coca-Cola's meritless waiver arguments, which were nowhere advanced in its brief in opposition to certiorari. *See* Pet. 8, 14, 15 (challenge to Coca-Cola's entire label, including the product's coloring, vignette, name, and label structure); S. Ct. R. 15.2; *Knowles* v. *Iowa*, 525 U.S. 113, 116 n.2 (1998).

Br. 12 (16 of 17 warning letters related only to nutrition labeling and health claims); Resp. Br. 51 n.39 (only three warning letters in the last year relating to misleading food labels).

Coca-Cola and its industry supporters are asking for dispensation from the rules applicable to the rest of the national economy. Under their preferred regime, "'assum[ing] the risk'" of selling a knowingly misleading product—as Coca-Cola did here—would mean assuming no risk at all. Pet. App. 35a. Congress has never given the slightest indication that it intended such an exemption, and there is no valid reason why this one industry should be accorded one.[17]

CONCLUSION

The judgment should be reversed.

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[17] Attempting to downplay the reach of its theory, Coca-Cola points (53) to the FTC Act's saving clause, which expressly "saves" from preclusion "the antitrust Acts and the Acts to regulate commerce." 15 U.S.C. §51. But "Acts to regulate commerce" is a defined term that excludes the Lanham Act, *see id.* §44.

Respectfully submitted.

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APRIL 2014

SUPPLEMENTAL BRIEF

RECORD AND BRIEFS

No. 12-761

Supreme Court, U.S.
FILED
DEC 10 2013
OFFICE OF THE CLERK

IN THE

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THE COCA-COLA COMPANY,

Respondent.

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SUPPLEMENTAL BRIEF FOR PETITIONER

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ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

SUPPLEMENTAL BRIEF FOR PETITIONER

Most of the United States' brief is devoted to explaining why the Ninth Circuit's reasoning is both wrong and in conflict with precedents of this Court. And the Solicitor General does not dispute the importance of the question presented. The government nonetheless suggests that the Court deny the petition. But the United States' limited arguments for denying review are unpersuasive.

I. THE UNITED STATES CONFIRMS THAT THE NINTH CIRCUIT'S DECISION RESTS ON THE FDA'S MERE REGULATORY AUTHORITY OVER FOOD LABELING

The United States' brief confirms that Coca-Cola's opposition to certiorari rests on a misunderstanding of the Ninth Circuit's decision rejecting Pom's Lanham Act challenge to Coca-Cola's label. Contrary to Coca-Cola's contention, the Ninth Circuit's decision did not rest on the FDA's asserted approval of Coca-Cola's label but rather on the FDA's mere regulatory authority in this area.

This is a classic false advertising case. Pom and Coca-Cola compete directly in the market for pomegranate juices. Pom sells juices that—as purchasers would naturally expect—overwhelmingly contain actual pomegranate juice, which is sought by health-conscious consumers. Pom's products include a pomegranate-blueberry juice. Coca-Cola sells and aggressively markets its competing "POMEGRANATE BLUEBERRY" juice, which it colors a deep purple and sells with a label containing a large image of each fruit. *See* Pet. 6-7. Coca-Cola's misleading label causes consumers to believe that the juice actually contains significant amounts of those fruits when in fact it contains only trivial amounts: 0.3% pomegranate juice and 0.2% blueberry juice.

Pom introduced survey evidence showing that consumers are in fact seriously misled. Pet. App. 32a-33a. Additionally, consumers who have discovered the false labeling have complained directly to Coca-Cola in record numbers. *Id.* 31a-32a. Coca-Cola's own documents produced in discovery state that the company decided that it was "willing to assume the risk" of "misleading" consumers about the fact that "the product has less

than 0.5% of pomegranate and blueberry juices." *Id.* 34a-35a.

Believing that it was losing sales of its pomegranate juices because of Coca-Cola's deceptive label, Pom brought this lawsuit under the Lanham Act. Pet. App. 3a. As is relevant here, that statute creates a private right of action against a person who uses a "false or misleading" description or representation "in connection with any goods" or "container for goods" that "misrepresents the nature, characteristics, [or] qualities" of those goods in commercial advertising or promotion. 15 U.S.C. § 1125(a)(1). Despite this unequivocal statutory text, the Ninth Circuit sweepingly held that no Lanham Act suit may be brought challenging the label of a product regulated under the Food, Drug, and Cosmetic Act ("FDCA"). Pet. App. 12a. The Ninth Circuit deemed it dispositive that the FDCA permits the FDA to determine that the juice is "misbranded" and forbid Coca-Cola from using a particular label. *Id.* 6a, 12a.

When Pom sought review in this Court, Coca-Cola's principal argument against certiorari was to try to recast the ruling below as if it forbids Lanham Act claims only with respect to a label that is "specifically authorized" by the FDA. Opp. 1, 4. According to Coca-Cola, the Ninth Circuit merely held "that the FDA's specific determination ... that juice labels like Coca-Cola's are not misleading precludes a private party from advancing the opposite position ... under the Lanham Act." *Id.* 10.

The invitation brief of the United States demonstrates that Coca-Cola's reading mischaracterizes the ruling below: "In short, the court's decision rested on what it perceived as 'Congress's decision to entrust matters of juice beverage labeling to the FDA and * * *

the FDA's comprehensive regulation of that labeling.'" U.S. Br. 10 (quoting Pet. App. 12a). Thus, "the court of appeals held that FDA's food-misbranding *authority* under the FDCA occupies the relevant field here to the *total exclusion* of" the Lanham Act. *Id.* 11 (emphasis added).

II. The United States Agrees With Pom That The Ninth Circuit Erred

The brief of the United States also explains that the Ninth Circuit's holding misinterprets the FDCA and conflicts with this Court's precedents.

A. The government agrees with Pom that the court of appeals erred in holding that a Lanham Act claim is precluded whenever the "FDA had not (but could have) regulated the aspects of the label about which petitioner complained." U.S. Br. 8-9. That is so because "the FDCA does not occupy the juice-labeling field." *Id.* 10. "[N]othing in the FDCA, the [Nutrition Labeling and Education Act of 1990], FDA's regulations, or the preambles to those regulations suggests that FDA has marked the metes and bounds of all possible misleading materials on juice labels, or that its authority must be deemed exclusive even as to matters the agency has never specifically addressed." *Id.* 11-12. The FDCA requires that a label contain a product's "common or usual name." 21 U.S.C. § 343(i). In turn, FDA regulations provide that it is consistent with the statute to name a product after a non-predominant juice if the product name identifies the juice as a "blend" and states that it is "flavored" with the non-predominant juice. 21 C.F.R. § 102.33(c)-(d). But the agency does not view it as its mission—and in any event it does not have the resources—to police the details of many thousands of juice labels to determine

which ones mislead consumers into making purchases without presenting any public health threat. Pet. 25-26.

As the government emphasizes, Congress did not intend that the subject matter of petitioner's suit would be exclusively regulated by the FDA, to the exclusion of the Lanham Act's unqualified remedy:

> Most fundamentally, petitioner's claim arises under the Lanham Act, and it does not rely for its success on FDA's regulations (or, therefore, on FDA's application of those regulations). FDA does not administer the Lanham Act, and it has no authority to resolve a competitor's claim of competitive injury due to a misleading label.

U.S. Br. 14. Further, the "FDA does not approve juice labels, and its failure to initiate an enforcement action cannot be construed as such an approval." *Id.* 16. "In short, FDA's expertise in this field is not deployed in a way that justifies categorically depriving petitioner of a cause of action under Section 43(a) of the Lanham Act." *Id.* 15.[1]

B. The United States further agrees with Pom that, for those reasons, the ruling below cannot be reconciled with this Court's precedents. Absent clearly expressed congressional intent to the contrary, one federal statute does not displace another if the two are "'capable of coexistence.'" U.S. Br. 9 (quoting *J.E.M. Ag Supply, Inc.* v. *Pioneer Hi-Bred Int'l, Inc.*, 534 U.S.

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[1] The government also notes that the ruling below creates the "implausible" result that the FDCA precludes an action under the Lanham Act while preserving parallel state remedies. U.S. Br. 11 (citing 21 U.S.C. § 343-1).

124, 143 (2001)). The Court's precedents provide—and Congress legislates against the settled understanding—that two statutes will be given effect unless they are in "'irreconcilable conflict,' or where the latter Act covers the whole subject of the earlier one and 'is clearly intended as a substitute.'" *Branch* v. *Smith*, 538 U.S. 254, 273 (2003) (quoting *Posadas* v. *National City Bank*, 296 U.S. 497, 503 (1936)). No such conflict exists here. *See* U.S. Br. 10-15. The United States confirms that "Congress has repeatedly amended both" the FDCA and the Lanham Act, never suggesting that the former limits the latter. *Id.* 13. "If Congress intended to foreclose such suits, it could easily have done so." *Id.*

It is uncontested—and dispositive—that Coca-Cola can easily comply with the Lanham Act by not using a label that misleads consumers while also employing the juice's "usual or common name" under the FDCA and the FDA's regulations. As this Court has held (in a decision the Ninth Circuit failed to cite), the FDCA sets a "floor"—not a ceiling—on federal regulation of labels. *Wyeth* v. *Levine*, 555 U.S. 555, 577-578 (2009). Indeed, the FDA indicated that it "encourages" manufacturers to declare "each juice in a beverage ... in the name of the product." 58 Fed. Reg. 2897, 2919 (Jan. 6, 1993). It has also rejected the proposition that compliance with the requirements of one portion of its regulations insulates a label from review.[2]

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[2] *See* Warning Letter from Roberta F. Wagner, FDA, to Brad Alford, Nestle U.S.A., Dec. 4, 2009, *available at* http://www.fda.gov/iceci/enforcementactions/warningletters/ucm194122.htm (asserting that juice blend labels similar to Coca-Cola's were "misleading" because of the large prominent font used for the non-predominant juice, the proximity of the juice name to the words

C. Coca-Cola can take no solace from the fact that the government believes the Ninth Circuit's erroneous reasoning reached the correct result in one respect. The United States agrees with Pom that the Ninth Circuit erred in forbidding Pom from "challeng[ing] aspects of respondent's juice label that are not specifically addressed by the FDCA or FDA's regulations," including "'*how* [respondent] presents the words "Pomegranate Blueberry" and "Flavored Blend of 5 Juices" on the product's label.'" U.S. Br. 18-19 (emphasis added) (quoting Pet. App. 10a). On the other hand, the government contends that Pom's Lanham Act claim is impliedly precluded with respect to "the common name of respondent's juice"—*i.e.*, "Pomegranate Blueberry"—"because that claim sought to impose liability for what FDA's regulations under the FDCA had specifically permitted." *Id.* 8.

Whatever the merit of the theoretical distinction between the product's name and its label, that distinction has no practical consequence. Consumers see the entire product label (or product advertisement), not merely the product's name. In the context of a false advertising claim, it is meaningless to say that the name "Pomegranate-Blueberry" juice is not misleading without accounting for how that name is depicted along with, for example, images of those fruits and the fact that the label describes the juice as a "blend" only in a much smaller font. As the Solicitor General elsewhere

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"All Natural 100% Juice," and the fact that the "flavored" and "blend" caveats were at the bottom of the labels in small, white font); *see also, e.g.*, 21 C.F.R. § 102.5(b) (imposing limitations on the ability to use juice names like that chosen by Coca-Cola).

emphasizes, the "FDA specifically cautioned manufacturers who would take advantage of 21 C.F.R. 102.33(b)-(d) about the potential for their labels to mislead." U.S. Br. 19.

D. To the extent the distinction drawn by the Solicitor General might have any force, it only highlights that this case is an ideal vehicle to decide the question presented. As the government recognizes, Pom challenges the label of Coca-Cola's product with respect to both the product's name (a claim the government says is precluded) and the way the label is presented (which it says is not precluded). U.S. Br. 8, 17-19. This case accordingly provides this Court an excellent opportunity to explore the potential preclusive effect of the FDCA and the FDA's regulations with respect to both allegations and their relationship to each other. Later cases, by contrast, may present only one allegation or the other.

The government's contrary argument that this case may not present an ideal vehicle to decide the question presented lacks merit. The government says that one aspect of petitioner's *proof* of its Lanham Act claim—a consumer survey—found that Coca-Cola's label was misleading, without distinguishing those two features of the label. U.S. Br. 21. The obvious answer is that the question presented does not ask this Court to evaluate the evidence that could be cited on remand in support of Pom's claim. It is asking the Court to hold that Pom's suit under the Lanham Act may proceed, in whole or in part. Pom's challenges to the name and label of Coca-Cola's product were rejected as a matter of law at the motion to dismiss stage. *See* Pet. App. 85a-92a. That rejection was then confirmed—again as a matter of law—at the summary judgment stage. *See id.* 60a-65a. The legal question presented by the peti-

tion does not turn on whether Pom's consumer survey anticipated the distinction the government now draws regarding which types of Lanham Act claims would proceed. Put another way, the government cannot and does not explain how this Court's interpretation of the Lanham Act, the FDCA, or the FDA's regulations turns on which question Pom's expert asked consumers.

III. There Is No Merit To The United States' Attempt To Minimize The Circuit Conflict On This Important Question

A. The petition demonstrates that the ruling below creates a square conflict with decisions of the Third, Eighth, and Tenth Circuits. Pet. 19-24. Coca-Cola itself acknowledges that those other courts broadly hold "that false or misleading product labels are actionable under the Lanham Act even though they are regulated by FDA." Opp. 16. The government recognizes the "tension" between the ruling below and those decisions. U.S. Br. 20. It also makes the important point that the ruling below disrupts the previously uniform understanding that competitors may bring "challenges to food labels under Section 43(a) of the Lanham Act." *Id.* (citing decisions of the Fourth, Seventh, and Eighth Circuits).

The Solicitor General nonetheless maintains that there is not a sufficiently "*[d]eveloped*" circuit conflict, U.S. Br. 19 (emphasis added), because the ruling below "misinterpreted the preclusive reach of the FDCA provisions that apply to food," whereas the cases in other courts of appeals involved products other than food, *id.* 9. The United States does not explain why that distinction makes a legal difference or why this Court should review seriatim numerous cases involving the preclu-

sive effect of distinct FDA regulatory schemes rather than providing the lower courts with guidance in this one, well-presented case. The government's position is that the FDCA precludes a Lanham Act suit when the FDA issues an on-point regulation, whereas the Lanham Act applies when the agency does not act in that fashion. That view has nothing to do with whether the subject matter of the agency's regulation is "food" or something else. Indeed, the lower courts have applied the "seemingly categorical breadth of the court of appeals' logic," *id.* 13, well beyond food labels regulated under the FDCA to other types of products. *See, e.g.*, *All One God Faith, Inc.* v. *Hain Celestial Grp., Inc.*, No. 09-3517, 2012 WL 3257660, at *1-11 (N.D. Cal. Aug. 8, 2012) (Lanham Act challenging false label of personal care and cosmetic products as "organic" barred by USDA's authority to regulate such products under the Organic Food Products Act of 1990).

Further, the regulatory schemes that other circuits did not find to be preclusive were no less comprehensive than the FDA's regulation of food products:

- *Sandoz Pharmaceuticals Corp.* v. *Richardson-Vicks, Inc.*, 902 F.2d 222, 226-227 (3d Cir. 1990), involved the FDA's and FTC's extensive regulatory authority with respect to over-the-counter drug advertising and labeling. *See* 15 U.S.C. §§ 45, 52; 21 C.F.R. §§ 201.1-201.26, 201.60-201.80.

- *Alpharma, Inc.* v. *Pennfield Oil Co.*, 411 F.3d 934, 935 (8th Cir. 2005), addressed FDA approval of new animal drugs, which are subject to extensive FDA regulation. *See* 21 U.S.C. § 360b; 21 C.F.R. §§ 500.23-589.2001.

- *Cottrell, Ltd.* v. *Biotrol International, Inc.*, 191 F.3d 1248 (10th Cir. 1999), involved the labeling and advertising of pesticides regulated by the EPA under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") in a manner similar to the FDA's regulation under the FDCA. *See id.* at 1250 & n.1 (noting that FIFRA provides "a detailed regulatory framework for registering pesticides ... including provisions for approving pesticide labels and claims made therein."); *id.* at 1255 (noting similarity to FDA regulation); *see also* 7 U.S.C. §§ 136-136y; 40 C.F.R. §§ 152.1-152.500.

Because those decisions each involve the identical legal issue, they represent a coherent and recognized body of law that does not turn on the particular regulatory scheme at issue. The Ninth Circuit in this case purported to rely on *Sandoz* as well as its prior decision in *PhotoMedex, Inc.* v. *Irwin*, 601 F.3d 919 (9th Cir. 2010), which addressed marketing of a medical device subject to FDA regulation. *See* Pet. App. 7a. *PhotoMedex*, in turn, relied on *Sandoz* and discussed *Alpharma*. *See* 601 F.3d at 928-930. *Cottrell* and *Alpharma* relied on *Sandoz*. *See* 191 F.3d at 1253; 411 F.3d at 938-940. In fact, in assessing whether the Ninth Circuit erred in this case, the United States relied upon *Alpharma* and *Cottrell* as well as *Schering-Plough Healthcare Products, Inc.* v. *Schwarz Pharma, Inc.*, 586 F.3d 500 (7th Cir. 2009), which involved an over-the-counter drug regulated by the FDA. *See* U.S. Br. 13, 15-16.

B. The United States does not dispute the importance of the question presented. Even if it were limited to food products, the ruling below grants tens of thousands of food and juice producers sweeping immun-

ity with respect to countless products from liability under the Lanham Act for even knowingly misleading consumers. *See* Pet. 26-27. The government recognizes that the court's "deference to FDA's available but unexercised authority would arguably preclude a Lanham Act challenge to the label of *any* food," including "the many foods that FDA's regulations do not specifically address at all." U.S. Br. 12. As the GAO has confirmed, the FDA "'generally does not address misleading food labeling because it lacks the resources to conduct the substantive, empirical research on consumer perceptions.'" Pet. 26 (quoting GAO Report 30). The Ninth Circuit's decision thus would upset a longstanding statutory scheme that permits both Lanham Act challenges to, and FDA regulation of, food and other product labels in favor of exclusive regulation by a governmental agency that acknowledges it lacks the resources for such a role. Under the Ninth Circuit's field-preemption holding, private enforcement of the Lanham Act would be precluded whenever there is allegedly "comprehensive" agency regulation. Pet. App. 12a. The United States does not dispute that such a holding would have significant consequences.

CONCLUSION

For the foregoing reasons, Pom's petition for a writ of certiorari should be granted.

Respectfully submitted.

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DECEMBER 2013

SUPPLEMENTAL BRIEF

RECORD AND BRIEFS

12-761

Supreme Court, U.S.
FILED
DEC 17 2013
OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

POM WONDERFUL LLC,

Petitioner,

—v.—

THE COCA-COLA COMPANY,

Respondent.

ON PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

SUPPLEMENTAL BRIEF FOR RESPONDENT

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SUPPLEMENTAL BRIEF FOR RESPONDENT

The United States correctly recommends that this Court deny certiorari because, *inter alia*, there is no circuit conflict (U.S. Br. 19-21) and the FDA has adequate resources to regulate the content of food and juice labels (U.S. Br. 15, 17-18).

I. THE UNITED STATES CONFIRMS THAT NO CIRCUIT CONFLICT IS PRESENTED

Petitioner originally (Pet. 19-24), and again in its supplemental brief (Pet. Supp. Br. 9-11), alleges a conflict between the Ninth Circuit's decision below, on the one hand, and decisions of the Third (*Sandoz Pharm. Corp.* v. *Richardson-Vicks, Inc.*, 902 F.2d 222 (1990)), Eighth (*Alpharma, Inc.* v. *Pennfield Oil Co.*, 411 F.3d 934 (2005)), and Tenth (*Cottrell, Ltd.* v. *Biotrol Int'l, Inc.*, 191 F.3d 1248 (1999)) Circuits, on the other hand. Petitioner is incorrect, as the United States agrees (U.S. Br. 19-21).

a. *Sandoz* does not conflict with the decision below because, most obviously, both decisions *rejected* a Lanham Act claim. See *Sandoz*, 902 F.2d at 232; Pet. App. 10a. The Third Circuit reasoned in *Sandoz* that the proposed Lanham Act claim would require resolution of a question that the FDA had not yet answered: whether consumers would be misled by the defendant's labeling of a certain cough-syrup ingredient as "inactive." 902 F.2d at 231 ("Sandoz's position would require us to usurp administrative agencies' responsibility for interpreting and enforcing potentially ambiguous regulations."). This holding applies *a fortiori* here because the issue whether a multi-fruit juice name or label is deceptive is not

only within the FDA's expertise, but is a topic that the FDA *has already addressed* in detailed and specific regulations.

First, as to the name, 21 C.F.R. § 102.33(d)(1) authorizes a name that "[i]ndicate[s] that the named juice is present as a flavor or flavoring (e.g., 'Raspcranberry'; raspberry and cranberry flavored juice drink)." FDA adopted this regulation only after "discuss[ing] at length why it would not be misleading to describe such a beverage as 'flavored' with a non-predominant juice, even while not listing by name or percentage the other juices present." U.S. Br. 18 (citing 58 Fed. Reg. 2897, 2918-2921 (Jan. 6, 1993)). As the United States correctly observes, the regulation "reflect[s] the agency's balance of competing considerations in a specific setting that could easily be upset by the intrusion of a general private remedy such as that provided under Section 43(a) of the Lanham Act." U.S. Br. 18;[1] see also *ibid.* (explaining further, in accord with respondent's brief in opposition (at 9), that a Lanham Act Section 43(a) claim "is not 'capable of coexistence' with those [FDA] regulations" and therefore may not be asserted) (quoting *J.E.M. Ag Supply, Inc.* v. *Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 143 (2001)).

Second, as to the relative font sizes of "POMEGRANATE BLUEBERRY" and "FLAVORED BLEND OF 5 JUICES" (see Pet. App. 2a), accepting

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[1] See also Pet. App. 10a (decision below) ("In extensively regulating the labeling of foods and beverages, the FDCA and its implementing regulations have identified the words or statements that must or may be included on labeling ....").

arguendo the United States' view that the FDA has *not* yet specifically regulated this issue (U.S. Br. 19), *Sandoz* is on all fours with the decision below. Both in *Sandoz*, and in this case concerning the font-size issue as the United States conceives it, the FDA has authority to regulate the issue but has not yet done so. Compare *Sandoz*, 902 F.2d at 231 ("We decline to find ... that which the FDA, with all of its scientific expertise, has yet to determine."), with U.S. Br. 19 ("[T]he FDCA and FDA have not specifically addressed 'how [respondent] presents the words 'Pomegranate Blueberry' and 'Flavored Blend of 5 Juices' on the product's label.'") (quoting Pet. App. 10a). In fact, the United States and petitioner overlook that FDA has specifically addressed the font-size issue in 21 C.F.R. § 101.22(i)(1)(i), which provides that the "characterizing flavor ... shall be immediately followed by the word 'flavored' *in letters not less than one-half the height of the letters in the name of the characterizing flavor*" (emphasis added). Here, the letters "FLAVORED BLEND OF 5 JUICES" comply with this specific regulation because, as is clear from the image at Pet. App. 2a, they are *more* than one-half the height of the words "POMEGRANATE BLUEBERRY."[2] Thus, *Sandoz* applies *a fortiori* here with respect to the font-size issue just as it does with respect to the name issue.

b. *Alpharma* and *Cottrell* do not conflict with the decision below because, unlike here, the Lanham Act

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[2] The FDA has explained that 21 C.F.R. § 101.22(i)(1)(i) applies to blended juices such as the one at issue here. See 56 Fed. Reg. 30,452, 30,462, Proposed Rule (July 2, 1991) ("Any pertinent provisions in § 101.22(i) are applicable to the labeling of the various juice beverages.").

claim in those cases was that the defendant had misrepresented that a federal agency had approved its product. *Alpharma*, 411 F.3d at 935 (plaintiff alleged that defendant "falsely advertis[ed] that one of its antibiotic animal feed additives was approved for certain uses by the [FDA]"); *Cottrell*, 191 F.3d at 1254 (plaintiff alleged that defendant's "advertising deceives customers 'by implying that EPA approval or clearance has been obtained [for the seven-day efficacy claim]'") (brackets in original). Here, by contrast, petitioner's Lanham Act claim *does not allege that respondent's label made any representation that the FDA had approved the label or the juice*; rather, petitioner's claim does not concern FDA approval and instead alleges that respondent's label misleads consumers as to the content of the juice. See Pet. Supp. Br. 2 ("Coca-Cola's misleading label causes consumers to believe that the juice actually contains significant amounts of [pomegranate and blueberry juice] when in fact it contains only trivial amounts.").

There is good reason to distinguish between a representation as to agency approval, on the one hand, and a representation as to the content of a juice, on the other hand. The determination whether a defendant has or has not obtained regulatory approval (which in turn will decide whether the representation as to such approval is misleading) is generally a true-or-false determination that calls for no particular agency expertise and can be made in the course of court adjudication of a private Lanham Act claim. By contrast, a determination whether other labeling content (not involving a representation as to agency approval) is misleading often does call for second-guessing the agency's expertise. As the Seventh Circuit explained:

> The FDA should be given a chance to opine on the proper labeling before a Lanham Act suit is filed since it has more experience with consumers' understanding of drug labels than judges do. *Alpharma*, in contrast, was a case in which the complaint under the Lanham Act was simply that the defendant had said that the FDA had approved its drug for a number of uses for which it had not been approved. Evaluating such a charge did not draw on the agency's insights into the understanding of consumers of drugs; allowing the suit to proceed without reference to the agency was therefore not objectionable as an attempt to use the Lanham Act as a vehicle for enforcing the Food, Drug, and Cosmetic Act, which does not authorize a private right of action.

Schering-Plough Healthcare Prods., Inc. v. *Schwarz Pharma, Inc.*, 586 F.3d 500, 508-09 (7th Cir. 2009) (internal citations omitted).

While the United States criticizes *Schering-Plough* as endorsing the view that the FDA's mere authority to regulate a particular drug label suffices to preclude a Lanham Act claim (U.S. Br. 14), that issue is not presented by the decision below and this case is therefore an improper vehicle in which to resolve the issue. As explained above, and as the Ninth Circuit correctly held, this case does not involve an as-yet unexercised power of the FDA, but specific FDA regulations that squarely address the naming and font-size issues of blended juice. See *supra*, at 2-3; Pet. App. 10a ("[T]he FDCA and its implementing regulations have identified the words or

statements that must or may be included on labeling and have specified how prominently and conspicuously those words and statements must appear.").[3]

c. The United States correctly observes that there is no conflict between the decision below and decisions that have proceeded to the merits of Lanham Act claims challenging food labels. See U.S. Br. 20. None of those decisions addressed whether a specific FDA regulation precluded the Lanham Act claim, and for good reason—unlike here, there was no specific FDA regulation in place concerning a label's claim regarding the popularity of the product or its quality compared to competitors' products. See *Mead Johnson & Co.* v. *Abbott Labs.*, 201 F.3d 883, 884 (7th Cir.) (formula is "1st Choice of Doctors"), cert. denied, 531 U.S. 917 (2000); *PBM Prods., LLC v. Mead Johnson & Co.*, 639 F.3d 111, 116-17 (4th Cir. 2011) (formula "[c]ompare[s] to [competitor brand]");[4] *American Italian Pasta Co. v. New World Pasta Co.*, 371 F.3d 387, 389 (8th Cir. 2004) (pasta is "America's Favorite Pasta").

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[3] Given this passage in the Ninth Circuit's decision below, the United States' suggestion that the Ninth Circuit's reasoning turned on the FDA's mere authority to regulate fruit juice labels (U.S. Br. 10) is incorrect. In any event, as the United States recognizes (U.S. Br. 19-21), this Court does not typically grant certiorari to review the *reasoning* of a circuit's decision where that decision is entirely consistent in *outcome* with decisions by other circuits.

[4] The FDA has extensively regulated labeling of infant formula, *e.g.*, 21 C.F.R. 107, Subpart B, but not the specific matter of claims regarding a formula's popularity or a formula's quality as compared to competitors' formulas.

II. THE UNITED STATES CONFIRMS THAT THE FDA HAS ADEQUATE RESOURCES TO REGULATE FOOD AND JUICE LABELS

This Court may have called for the view of the Solicitor General to advise on the correctness of petitioner's hyperbolic assertion that "the FDA woefully lacks the resources necessary" to regulate food labels (Pet. 25).

The United States' invitation brief provides reassurance that the FDA indeed has adequate resources. Specifically, the United States recounts that "FDA discussed *at length* why it would not be misleading to describe ... a beverage as 'flavored' with a non-predominant juice, even while not listing by name or percentage the other juices present." U.S. Br. 18 (citing 58 Fed. Reg. at 2918-2921) (emphasis added). The United States also recognizes that the FDA's regulatory effort in this area "reflect[s] the agency's balance of competing considerations in a specific setting that could be easily upset by the intrusion of a general private remedy such as that provided under Section 43(a) of the Lanham Act." U.S. Br. 18. And the United States acknowledges the FDA's ability "to undertake a rulemaking to revise its labeling regulations for juice mixtures" (U.S. Br. 15) without casting any resource-related doubt on that ability.

CONCLUSION

The petition for a writ of certiorari should be denied.

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December 17, 2013

AMICUS CURIAE BRIEF

RECORD
AND
BRIEFS

Supreme Court, U.S.
FILED
MAR 3 - 2014
OFFICE OF THE CLERK

No. 12-761

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POM WONDERFUL LLC, PETITIONER

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THE COCA-COLA COMPANY

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING NEITHER PARTY

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QUESTION PRESENTED

Whether and to what extent the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*, and regulations promulgated under that Act, preclude a food manufacturer from challenging the label of its competitor's product under Section 43(a) of the Trademark (Lanham) Act of 1946, 15 U.S.C. 1125(a), which provides a cause of action against anyone who, *inter alia*, "uses in commerce any word, term, name, symbol, or device, or any combination thereof * * * which * * * misrepresents the nature, characteristics, [or] qualities * * * of his * * * goods." 15 U.S.C. 1125(a)(1) and (B).

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INTEREST OF THE UNITED STATES

This case concerns whether and to what extent the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.*, and regulations promulgated thereunder, preclude a food manufacturer from challenging the label of its competitor's product under Section 43(a) of the Trademark Act of 1946 (Lanham Act), 15 U.S.C. 1125(a). By virtue of the regulatory and enforcement responsibilities of the Food and Drug Administration (FDA), and shared enforcement authority of the Federal Trade Commission (FTC), the United States has a substantial interest in that issue. At the Court's invitation, the Solicitor General filed an amicus brief on behalf of the United States at the petition stage of this case.

STATEMENT

1. a. "Congress has regulated food and beverage labeling for more than 100 years." *Holk* v. *Snapple Beverage Corp.*, 575 F.3d 329, 331 (3d Cir. 2009). It did so first in the Federal Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768, then in the Federal Food, Drug, and Cosmetic Act (FDCA), ch. 675, 52 Stat. 1040 (21 U.S.C. 301 *et seq.*), and later through amendments to the FDCA. In 1990, Congress amended the FDCA to address nutrition labeling for nearly all food products for human consumption, including juices. Nutrition Labeling and Education Act of 1990 (NLEA), Pub. L. No. 101-535, 104 Stat. 2353. Throughout those efforts, "[m]isbranding was one of the chief evils Congress sought to stop." *62 Cases of Jam* v. *United States*, 340 U.S. 593, 596 (1951).

The FDCA bans the introduction into or receipt in interstate commerce of "misbranded" foods. 21 U.S.C. 331(a) and (c). "Food" includes any "article[] used for food or drink for man." 21 U.S.C. 321(f). Of relevance here, a food is misbranded if "its labeling is false or misleading in any particular," 21 U.S.C. 343(a)(1); if required information is not sufficiently prominent and conspicuous on the label or labeling, 21 U.S.C. 343(f); or if its label fails to bear "the common or usual name of the food, if any there be, and * * * in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient," 21 U.S.C. 343(i)(1) and (2).[1]

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[1] The FTC shares with FDA enforcement authority over deceptive food labeling, advertising, and promotion. See 15 U.S.C. 45(a)(2), 52(a); 36 Fed. Reg. 18,539 (Sept. 16, 1971) (memorandum of understanding). Although the parties do not contend that the FTC's enforcement authority bears on the viability of petitioner's claim,

To implement those provisions, and to "promote honesty and fair dealing in the interest of consumers," 21 U.S.C. 341, FDA has regulated many aspects of the naming and labeling of juices and juice beverages. See, *e.g.*, 58 Fed. Reg. 2897-2926 (Jan. 6, 1993) (removing and promulgating scattered Sections of 21 C.F.R. Pts. 101, 102).[2] Particularly relevant here are provisions of 21 C.F.R. 102.33 that govern the "common or usual name" for multiple-juice beverages:[3]

- Under Section 102.33(b), juices identified by name on the label (other than in the ingredient statement)—"named juices" for short—"must be [named] in descending order of predominance by volume unless the name specifically shows that [a nonpredominant] juice [supplying a] represented flavor is used as a flavor (e.g., raspberry-flavored apple and pear juice drink)."
- Under Section 102.33(c), if a named juice is not the only juice present, "then the common or usual

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the breadth of the court of appeals' reasoning could intrude on that authority.

[2] Although FDA's juice-labeling regulations also implemented certain provisions of the NLEA, including one specific to juice labeling, those provisions are not directly at issue here. See NLEA § 7(2), 104 Stat. 2364 (21 U.S.C. 343(i)(2)) (declaring beverage containing fruit juice misbranded if it does not contain "a statement with appropriate prominence on the information panel of the total percentage of such fruit * * * juice contained in the food"); 58 Fed. Reg. at 2899-2901 (interpreting that provision as requiring disclosure of the total percentage of juice in the product); 21 C.F.R. 101.30.

[3] The "common or usual name of a food may be established by," *inter alia*, "common usage or by establishment of a regulation in subpart B of [Part 102]." 21 C.F.R. 102.5(d); see 21 C.F.R. 101.3(b) and (e)(3).

name for the product shall indicate that the [named] juice is not the only juice present (e.g., 'Apple blend; apple juice in a blend of two other fruit juices.')."

- Under Section 102.33(d), if a named juice is not the only juice present and is not the predominant juice, then the "common or usual name for the product shall" either (1) "[i]ndicate that the named juice is present as a flavor or flavoring (e.g., 'Raspcranberry'; raspberry and cranberry flavored juice drink)" or (2) "[i]nclude the amount of the named juice, declared in a 5- percent range * * * in the manner set forth in [Section] 102.5(b)(2)."

The foregoing requirements are not privately enforceable. See 21 U.S.C. 337(a) ("[A]ll such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States."); *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001). In addition, in a provision added by the NLEA, the FDCA expressly preempts any State from "directly or indirectly" establishing any requirement "that is not identical" to, *inter alia*, certain food-misbranding provisions that include 21 U.S.C. 343(f), (i)(1) and (2), but not 21 U.S.C. 343(a). See 21 U.S.C. 343-1(a). The FDCA does not expressly address its relationship to other federal laws.

b. The Lanham Act amended existing trademark law to make "actionable the deceptive and misleading use of marks" in interstate commerce, to "protect persons engaged in such commerce against unfair competition," and to "provide rights and remedies stipulated by treaties and conventions respecting trademarks, trade names, and unfair competition entered into between the

United States and foreign nations." 15 U.S.C. 1127. As amended, Section 43(a) of the Lanham Act creates a private civil action against

> [a]ny person who, on or in connection with * * * any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof * * * which * * * misrepresents the nature, characteristics, [or] qualities * * * of his * * * goods.

15 U.S.C. 1125(a)(1) and (B). Such an action may be brought "by any person who believes that he or she is or is likely to be damaged by such act." 15 U.S.C. 1125(a)(1).

2. Petitioner "produces, markets and sells bottled pomegranate juice and pomegranate juice blends, including a pomegranate blueberry juice blend." Pet. App. 1a. Respondent, doing business "under the brand Minute Maid, is one of [petitioner's] primary competitors in the bottled pomegranate juice market." *Id.* at 84a. In 2007, respondent announced a new product consisting of "99.4% apple and grape juices, 0.3% pomegranate juice, 0.2% blueberry juice, and 0.1% raspberry juice." *Id.* at 1a-2a. The product's front label displays a graphic vignette depicting grapes, blueberries, and raspberries in front of a halved pomegranate and halved apple. Below the vignette appear the words "Pomegranate Blueberry" in the same type but on separate lines; below "Blueberry," in smaller type, are the words "Flavored Blend Of 5 Juices"; below that, in still smaller type and separated by a blank line, are the words "From Concentrate With Added Ingredients"; and, finally, below those words in the same type are the further words "And Other Natural Flavors." See *id.* at 2a (reproducing label); Pet. Br. 9 (same).

3. In 2008, petitioner sued respondent under Section 43(a) of the Lanham Act.[4] Pet. App. 3a. Petitioner challenged the name, label, marketing, and advertising of respondent's juice, alleging that they mislead consumers to believe that respondent's juice consists predominantly of pomegranate and blueberry juices when it in fact consists predominantly of less expensive apple and grape juices, thereby injuring petitioner as a competitor. *Id.* at 84a-85a. Petitioner described respondent's juice label as containing "many misleading elements not required by federal or state regulation." J.A. 61a. And petitioner sought damages, recovery of respondent's profits, and an injunction barring further false advertising of respondent's juice. J.A. 64a-65a, 68a-69a.

The district court granted partial summary judgment to respondent on the Lanham Act challenges relating to the juice's name and label, finding those claims precluded. Pet. App. 21a-73a.[5] The court believed that "FDA has directly spoken on the issues that form the basis of" petitioner's claim in 21 C.F.R. 102.33(c) and (d), and that the juice's name is "expressly permitted (required here) by the FDA." Pet. App. 65a. The court further noted that 21 U.S.C. 343(f) requires only that respondent "prominently place the label on the Juice's bottle," which respondent "does sufficiently," Pet. App. 63a-64a; that petitioner failed to identify any regulation providing that

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[4] Petitioner also brought claims under various California laws. The district court found those claims expressly preempted. No. 08-cv-6237, 2013 WL 543361 (C.D. Cal. Feb. 13, 2013). Petitioner appealed, No. 13-55770 (9th Cir.), and those proceedings have been stayed pending resolution of this case.

[5] Petitioner later stipulated to dismissal of the advertising and marketing claims, Pet. App. 17a-19a, and subsequent proceedings have been limited to material on the juice's label.

the name "must appear on one single line, must be in one font, or must be centrally located" on the bottle, *id.* at 63a; and that the fruit vignette on respondent's label is "within the FDA's purview" and "clearly complies with FDA requirements," *id.* at 65a-67a.

4. The court of appeals affirmed in relevant part. Pet. App. 1a-14a. It began by describing the FDCA as "comprehensively regulat[ing] food and beverage labeling." *Id.* at 6a. Next, acknowledging that "the Lanham Act and the FDCA can conflict with each other" but should each be given "as much effect * * * as possible," the court identified several scenarios in which, in its view, "the FDCA limits claims under the Lanham Act." *Id.* at 6a-7a (internal quotation marks and citation omitted). "A plaintiff may not, for example, sue under the Lanham Act to enforce the FDCA or its regulations," or "maintain a Lanham Act claim that would require a court originally to interpret ambiguous FDA regulations," or pursue a Lanham Act "claim [that] would require litigating whether [certain] conduct violates the FDCA." *Id.* at 7a (citing cases illustrating those principles). On the whole, the court concluded that "the Lanham Act may not be used as a vehicle to usurp, preempt, or undermine FDA authority," but that a court must still "focus on the circumstances before it to strike a balance that disrupts the two statutory schemes as little as it can." *Id.* at 8a.

Applying those principles, the court of appeals concluded that "the FDCA and its regulations bar pursuit of both the name and labeling aspects of [petitioner's] Lanham Act claim." Pet. App. 9a. The court explained that, because 21 C.F.R. 102.33(d) permits a manufacturer to name a beverage using the name of a flavoring juice that is not predominant, "as best we can tell, FDA regulations authorize the name [respondent] has chosen." Pet.

App. 9a. Thus, the court reasoned, petitioner's challenge to the name "'Pomegranate Blueberry Flavored Blend of 5 Juices' would create a conflict with FDA regulations and would require [the court] to undermine the FDA's apparent determination that so naming the product is not misleading." *Ibid.*

The court of appeals likewise concluded that petitioner's Lanham Act claim was precluded with respect to the label's presentation of the words "Pomegranate Blueberry" in "larger, more conspicuous type" than the words "Flavored Blend of 5 Juices" appearing below them. Pet. App. 10a. The court believed that the FDCA and FDA regulations "have specified how prominently and conspicuously those words and statements must appear." *Ibid.* (citing 21 U.S.C. 343(f) and (i); 21 C.F.R. 102.33(c) and (d)). "Congress and the FDA have thus considered and spoken to what content a label must bear, and the relative sizes in which the label must bear it, so as not to deceive," but "ha[ve] not (so far as we can tell) required that all words in a juice blend's name appear on the label in the same size." *Ibid.* The court observed that "[i]f the FDA believes more should be done to prevent deception, or that [respondent's] label misleads consumers, it can act." *Id.* at 11a.

The court of appeals emphasized that it was not "hold[ing] that [respondent's] label is non-deceptive," or that "mere compliance with the FDCA or with FDA regulations will always (or will even generally) insulate a defendant from Lanham Act liability." Pet. App. 11a-12a. Rather, the court stated that it was guided by what it understood to be "Congress's decision to entrust matters of juice beverage labeling to the FDA and by the FDA's comprehensive regulation of that labeling." *Id.* at 12a. "In the circumstances here," the court concluded,

"the appropriate forum for [petitioner's] complaints is the [FDA]." *Ibid.* (citation omitted) (second set of brackets in original).

SUMMARY OF ARGUMENT

Petitioner's Lanham Act claim is barred only to the extent the FDCA or FDA regulations specifically require or authorize the challenged aspects of respondent's juice label. Because the court of appeals dismissed petitioner's claim in its entirety based on an overly broad view of preclusion, the decision below should be vacated and the case remanded for further proceedings.

A. FDA regulations specifically permit respondent to name its juice "Pomegranate Blueberry Flavored Blend Of 5 Juices," if pomegranate and blueberry juices are present as flavors or flavoring. Those regulations were adopted to address possible consumer confusion regarding the content of multiple-juice beverages, and the naming conventions FDA adopted were based on its considered determination that compliant names would not be misleading. To allow a Lanham Act challenge to a name that complies with those regulations would directly contravene FDA's judgment by declaring misleading what FDA determined to be nonmisleading.

It is true that the FDCA and its implementing regulations did not *require* respondent to name its juice "Pomegranate Blueberry," but impossibility is not the proper standard for finding preclusion here. FDA promulgated specific juice-naming regulations, pursuant to food-labeling provisions of the FDCA which predate the general private-right-of-action afforded under the Lanham Act. The naming regulations reflect the agency's balance of competing considerations, which could be easily upset by intrusion of a general private remedy.

Petitioner's suggestion that the name of respondent's juice may not, in fact, comply with FDA regulations rests in part on a misunderstanding of the governing regulations, and lacks support in the existing record. The lower courts should consider any unresolved factual questions in the first instance.

B. Petitioner's Lanham Act claim is not limited to the name of respondent's juice, and it should be allowed to proceed insofar as it challenges features of the juice's label not specifically required or authorized by the FDCA or FDA regulations.

The court of appeals erroneously found petitioner's entire Lanham Act claim barred based on a kind of "field" preclusion. An agency's mere authority to regulate in an area and its exercise of that authority to some extent are insufficient to impliedly preempt state law, let alone to bar an otherwise available federal remedy. Neither the FDCA nor FDA regulations purport to occupy the field of juice labeling. To the contrary, the carefully calibrated express preemption provision added to the FDCA by the NLEA in 1990, and FDA's regulatory approach, support a more nuanced inquiry.

Nor is categorical preclusion warranted to prevent courts from interpreting the FDCA or FDA regulations, to protect against "backdoor" private FDCA enforcement actions, or to preserve FDA's regulatory authority. Courts are called upon to interpret FDA regulations in various contexts. And the absence of a specific FDA regulation or enforcement action is neither indicative of a preference for no regulation nor a sign of tacit approval.

The courts below did not identify any statutory or regulatory provision specifically authorizing the other challenged features of respondent's juice label. Re-

spondent now points to 21 C.F.R. 101.22(i)(1)(i) as allowing the type-size on its label, but that reliance is misplaced. In any event, that provision would (at best) authorize a particular type-size for the word "flavored"; it would have no impact on the remainder of petitioner's labeling claim.

ARGUMENT

PETITIONER'S LANHAM ACT CLAIM IS PRECLUDED ONLY TO THE EXTENT THE FDCA OR FDA REGULATIONS SPECIFICALLY REQUIRE OR AUTHORIZE THE CHALLENGED ASPECTS OF RESPONDENT'S JUICE LABEL

This case concerns the interplay of two federal statutes that prohibit false or misleading statements in food labeling. "[W]hen two statutes are capable of coexistence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective." *J.E.M. Ag Supply, Inc.* v. *Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 143-144 (2001) (*J.E.M.*) (citation omitted). Although Section 43(a) of the Lanham Act and the FDCA overlap, in that each applies to the label of respondent's juice, they are generally capable of coexistence, *except* when a Lanham Act claim would prohibit what the FDCA or FDA regulations specifically require or permit. That approach gives maximum effect and respect to each statute.

The alternative approach to preclusion adopted by the court of appeals is too broad, and the approach advocated by petitioner is too narrow. On the one hand, FDA's authority to regulate juice labeling and its exercise of that rulemaking authority does not purport to occupy the field, and Lanham Act claims may often reinforce (not subvert) congressional and agency objectives. On the other, a Lanham Act claim that effectively challenges FDA regulations premised on a determination that cer-

tain information on a juice label would not be misleading would trench upon FDA's regulatory authority in a way that Congress did not intend.

Applying those principles, petitioner's challenge to the name of respondent's juice ("Pomegranate Blueberry Flavored Blend Of 5 Juices") is precluded if the named juices are present as flavors or flavoring. In those circumstances, FDA regulations specifically authorize respondent to choose that name, based on the determination that it would *not* be misleading to do so, and petitioner cannot now collaterally attack that determination in a Lanham Act suit contending that it *is* misleading. But petitioner's challenge to the presentation of the juice's name on the label (as opposed to what the name *is*) and to other aspects of the label that neither the FDCA nor FDA regulations specifically address should not be precluded.

A. Petitioner's Lanham Act Challenge To The Name Of Respondent's Juice Is Precluded If The Named Juices Are Present As Flavors Or Flavoring

An FDA regulation (21 C.F.R. 102.33) specifically permits respondent to name its juice "Pomegranate Blueberry Flavored Blend Of 5 Juices," if pomegranate and blueberry juices flavor the beverage. That regulation was adopted to address the potential for consumer confusion regarding the individual-juice content of multiple-juice beverages. The naming conventions FDA adopted were based on its considered judgment that compliant names would not themselves be misleading. A Lanham Act challenge to a name that complies with FDA's juice-naming regulation is precluded because it would directly contravene FDA's judgment by declaring misleading what that expert agency expressly found nonmisleading.

1. FDA regulations specifically permit a juice's name to include only juices present as flavors without declaring the percentage of named juices

Petitioner's name-based challenge rests on the undisputed fact that the predominant (and cheaper) juices in respondent's product are apple and grape and that (the more expensive) pomegranate and blueberry juices represent a collective 0.5% of that product. Pet. App. 1a-2a. Petitioner thus suggests that calling the juice "Pomegranate Blueberry" is misleading and that, perhaps, a more accurate name would be "Apple Grape." J.A. 61a; see J.A. 62a ("By name alone, one would expect that the primary ingredients * * * are pomegranate and blueberry juice."). In promulgating regulations, FDA considered that question and reached a different conclusion.

In 1993, FDA promulgated a regulation establishing a "common or usual name" for multiple-juice beverages. See 58 Fed. Reg. 2918-2923 (Jan. 6, 1993). That regulation (21 C.F.R. 102.33) makes three things clear. First, the name does not have to include all juices contained in the product, so long as it "indicate[s] that the represented juice is not the only juice present (e.g., 'Apple blend; apple juice in a blend of two other fruit juices.')." 21 C.F.R. 102.33(c). Second, the name does not have to include the predominant juices, so long as *either* (1) the name indicates that the nonpredominant juice "is present as a flavor or flavoring (e.g., 'Raspcranberry'; raspberry and cranberry flavored juice drink)," *or* (2) the amount of the nonpredominant juice is declared "in a 5- percent range (e.g., Raspcranberry; raspberry and cranberry juice beverage, 10- to 15-percent cranberry juice and 3- to 8-percent raspberry juice) * * * in the manner set forth in [Section] 102.5(b)(2)." 21 C.F.R.

102.33(d)(1)-(2). Third, and relatedly, the name does not have to include the percentage of the named juice contained in the product, so long as the named juice is "present as a flavor" and is designated as such. 21 C.F.R. 102.33(d)(1).

The name "Pomegranate Blueberry Flavored Blend Of 5 Juices" appears to be consistent with that regulation. Cf. pp. 22-23, *infra* (noting potential factual dispute). The name indicates that pomegranate and blueberry are not the only juices present (*i.e.*, "Blend Of 5 Juices") and that the named juices are present only as flavors or flavoring (*i.e.*, "Pomegranate Blueberry Flavored"). Indeed, the name of respondent's juice closely parallels examples that FDA offered as permissible common or usual names for juice mixtures. See 21 C.F.R. 102.33(c) ("apple juice in a blend of two other fruit juices"); 21 C.F.R. 102.33(d)(1) ("raspberry and cranberry flavored juice drink"); see also FDA, *A Food Labeling Guide* 9 (Jan. 2013) (*FDA Guide*), http:// www.fda.gov/downloads/Food/Guidance Regulation/UCM265446.pdf (same example for "beverage that is primarily white grape juice with raspberry and cranberry juices added"); *id.* at 11 ("cranberry-raspberry flavored juice drink in a blend of three other juices"); *id.* at 12 ("raspberry flavored fruit juice blend").

The juice-naming regulation was adopted after a lengthy rulemaking process. 56 Fed. Reg. 30,452 (July 2, 1991) (detailing 25-year history of juice-labeling regulations); see 58 Fed. Reg. at 2897 (agency received over 200 comments from, *inter alia*, consumers and consumer groups). The rulemaking focused on how to name multiple-juice beverages that contain minor amounts of "characterizing juice"—specifically, how to do so in a manner that would "accurately represent the contents of

the product while not providing misleading information to the consumer." 55 Fed. Reg. 3268 (Jan. 31, 1990); see 56 Fed. Reg. at 30,452, 30,455. And the agency homed in on the precise concern that petitioner raises here. See *id.* at 30,455 (acknowledging that "[m]any multiple-juice beverages * * * contain only a small amount of a highly flavored, expensive juice," and that the name of the product "[o]ften" suggests "that the expensive juice * * * is present in a substantial quantity, and that, therefore, the beverage is of good value, when in fact there is only a small amount of the juice present"); 58 Fed. Reg. at 2920 (noting agency's "aware[ness] of a number of products currently on the market for which the suggested labeling would not inform the consumer that the named juice is present in only a minor amount"); *id.* at 2920-2921 (recognizing that consumers can "be misled" when "the named juice is not the predominant juice"); see also 56 Fed. Reg. at 30,461, 30,462.

Alternatives were considered. See 45 Fed. Reg. 39,249-39,250 (June 10, 1980) (adopting final rule, never put into effect, requiring percentage declaration of each named juice in certain multiple-juice beverages)[6]; 49 Fed. Reg. 22,831-22,833 (June 1, 1984) (proposal to make individual-juice percentage declarations voluntary); 52 Fed. Reg. 26,691 (July 16, 1987) (proposal to make all percentage declarations voluntary); 55 Fed. Reg. at 3268 (listing several different approaches); 56 Fed. Reg. at 30,462 (commenter suggesting that consumers were mostly concerned with taste and that juices should be listed in order of flavor, not volume). And the proposed rule that preceded the 1993 regulation would have required a percentage declaration of every juice repre-

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[6] The effective date of that final rule was repeatedly delayed, and it never went into effect. See 56 Fed. Reg. at 30,452.

sented on the label (other than in the ingredient statement). 56 Fed. Reg. at 30,456, 30,465. But FDA ultimately rejected those approaches.

Instead, FDA provided "two alternative[]" ways to describe "the contribution of the named juice" when "one or more but not all the juices are named and the named juice is not the predominant juice." 58 Fed. Reg. at 2900; see *id.* at 2921 ("two labeling alternatives"). The agency explained why "using the term 'flavor' with the name of the characterizing juice will inform the consumer that the juice is present in an amount sufficient to flavor the beverage but will not imply that the content of that juice is greater than is actually the case." *Ibid.* And it concluded that the final rule (*i.e.*, 21 C.F.R. 102.33) is "adequate to prevent misleading labels on multiple-juice beverages." 58 Fed. Reg. at 2920; see *id.* at 2919 ("[I]t is not necessary to require that each juice in a beverage be named to ensure that the label is not misleading."); *ibid.* (describing examples as "nonmisleading ways" to name a multiple-juice beverage).

2. FDA's juice-naming regulation is not merely a "floor" that can be supplemented by the Lanham Act

To preserve the naming aspect of its Lanham Act claim, petitioner contends that its claim must survive unless there is an "irreconcilable conflict" between the two statutes (Br. 20-28), and that there is no such conflict here because FDA's juice-naming regulation merely sets a "floor" that standards imposed in a Lanham Act suit may supplement (Br. 32-40). That argument lacks merit.

a. Petitioner appears at times to argue that there is no "irreconcilable conflict" (Br. 22-23, 24-25) because it is not physically impossible to comply with both statutes. That argument fails for three reasons.

First, to the extent petitioner relies for this argument on the proposition that the FDCA did not impliedly repeal the Lanham Act (Br. 20-21), petitioner has the chronology wrong. The FDCA food-labeling provisions and FDA's authority to promulgate regulations implementing those provisions were enacted eight years before Section 43(a) of the Lanham Act. See FDCA §§ 401, 403(a), (f) and (i), 701(a), 52 Stat. 1046-1048, 1055; Lanham Act § 43(a), 60 Stat. 441. The question, then, would seemingly be whether the later-enacted statute (here, the Lanham Act) impliedly repealed the earlier-enacted statute (here, the FDCA). See *National Ass'n of Home Builders* v. *Defenders of Wildlife*, 551 U.S. 644, 662 (2007) ("repeals by implication are not favored") (citation and internal quotation marks omitted).

Second, the FDCA food-labeling provisions are "specific provision[s] applying to a very specific situation. [Section 43(a) of the Lanham Act], on the other hand, is of general application." *Morton* v. *Mancari*, 417 U.S. 535, 550 (1974). This Court has repeatedly made clear that, "[w]here there is no clear intention otherwise, a specific statute will not be controlled or nullified by a general one, regardless of the priority of enactment." *Id.* at 550-551; see *Radzanower* v. *Touche Ross & Co.*, 426 U.S. 148, 153 (1976) ("[A] statute dealing with a narrow, precise, and specific subject is not submerged by a later enacted statute covering a more generalized spectrum."). Here, it is not "absolutely necessary" to give the Lanham Act the construction petitioner urges in order to ensure that it has some meaning. *Ibid.* (citation omitted). To the contrary, under the government's interpretation, the FDCA's food-labeling provisions "will have no impact whatever upon the vast majority of lawsuits brought under that Act." *Id.* at 156. And even with respect to

juice labeling, a Lanham Act suit will lie where FDA has not promulgated regulations governing the particular issue or the defendant has not complied with such regulations.

Third, and relatedly, FDA's juice-naming regulation (which was adopted after the Lanham Act) speaks with even more specificity, and essentially serves to supply the standards to be applied in a Lanham Act suit in determining whether a juice name is misleading. None of the cases on which petitioner relies involved a conflict between specific agency regulations and a generally applicable statute. In this context, the task is to reconcile the statutory *and* regulatory schemes without intruding on one more than necessary to preserve the other.

b. Petitioner is also wrong to describe (Br. 32, 37) FDA's juice-naming regulation as merely a "floor" that can be supplemented by a Lanham Act suit without contravening its purpose. To be sure, respondent could have named its juice "apple grape juice blend," or "apple grape pomegranate blueberry raspberry juice," without running afoul of those regulations. And it could have identified the percentage of pomegranate and blueberry juices in the product name under Section 102.33(d)(2). But, contrary to petitioner's contention (Br. 22-25), "[t]he conflict" between the changes petitioner seeks to impose under the Lanham Act and FDA's juice-naming regulation "does not evaporate" because the "regulation simply permits, but does not compel," the name respondent chose. *Fidelity Fed. Sav. & Loan Ass'n* v. *de la Cuesta*, 458 U.S. 141, 155 (1982) (applying this principle in preemption context).

FDA, moreover, has never endorsed petitioner's all-or-nothing view of the agency's regulations. See Pet. Br.

34-37, 46-47. It is true that "compliance with one aspect of [FDA's] juice-naming regulations does not, by itself, render a juice label non-misleading." Pet. Br. 34-35; see p. 26, *infra*. But compliance with FDA's juice-naming regulations does make the juice's *name* nonmisleading. "FDA's enforcement position[]" (Pet. Br. 37) is entirely consistent with that understanding. FDA, for example, could not (and would not) bring an enforcement action against a manufacturer under 21 U.S.C. 343(a)(1) or (i) for naming its product "Raspcranberry; raspberry and cranberry flavored juice drink," if raspberry and cranberry juices were present as flavors, even if the drink was primarily white grape juice. See p. 14, *supra*.[7] Allowing the naming aspect of petitioner's claim to proceed in precisely those circumstances would not supplement FDA's enforcement resources (Pet. Br. 52-54); it would supplant FDA's regulatory judgment.

FDA's juice-naming regulation reflects the agency's "weigh[ing of] the competing interests relevant to the particular requirement in question." *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 501 (1996). And the agency "reached an unambiguous conclusion about how those competing considerations should be resolved." *Ibid.*; see 58 Fed. Reg. at 2920 ("These provisions are intended to provide manufacturers with flexibility for labeling products while providing consumers with information that they need to determine the nature of the product."). That balance

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[7] The warning letter petitioner cites (Br. 37 & n.6) did not find the juice labels misleading based on the juices' *name*; it found the labels misleading based on relative placement, lettering, type-size, spacing, and other similar features. See Letter from Roberta F. Wagner, FDA, to Brad Alford, Nestle U.S.A. (Dec. 4, 2009), http://www.fda.gov/iceci/enforcementactions/warningletters/ucm194122.htm.

could be easily upset by different legal rules imposed in a private suit such as that provided under Section 43(a) of the Lanham Act. Cf. *Geier* v. *American Honda Motor Co.*, 529 U.S. 861, 874-886 (2000) (explaining how imposition of a general tort duty there would frustrate a delicately crafted motor vehicle safety regulation intended to afford manufacturers flexibility). A successful challenge to a name that complies with FDA's juice-naming regulation would effectively negate that regulation. In those circumstances, the two statutes are no longer "capable of coexistence," *J.E.M.*, 534 U.S. at 143 (citation omitted), and the Lanham Act must give way.

Wyeth v. *Levine*, 555 U.S. 555 (2009), does not counsel otherwise. See Pet. Br. 32-40. In that case, the Court found that a state-law duty to provide a stronger drug warning would not obstruct the purposes of the federal regulation, even though FDA had pre-approved the drug's labeling. 555 U.S. at 573-581. That holding rested primarily on three factors that are absent here. First, Congress had *not* enacted an express preemption provision for prescription drugs, evidencing an intent that "FDA oversight" not be exclusive. *Id.* at 574-575. Second, FDA had at times described its labeling standards as a "floor" or as "minimum standards" and had suggested that common-law suits would be "complementary." *Id.* at 577-579. And third, the factual record suggested that FDA did not give "more than passing attention," *id.* at 572-573 (citation omitted), to the risk at issue and did not affirmatively "consider and reject a stronger warning," *id.* at 581 n.14. Here, in contrast, Congress enacted a provision that expressly preempts state law with respect to a food's name, 21 U.S.C. 343-1(a)(2) and (3) (albeit, not a provision that expressly precludes application of other federal laws); there is nothing "com-

plementary" about federal or state courts second-guessing FDA's juice-naming regulation and the agency has never suggested otherwise; and FDA extensively considered the precise issue in notice-and-comment rulemaking, see pp. 13-16, *supra*.

3. Petitioner's argument that respondent's juice name may not comply with FDA regulations is unsupported by the existing record

Petitioner now briefly contends (Br. 49-52) that the name of respondent's juice may not, in fact, comply with FDA regulations. Petitioner's arguments misconstrue the regulations and lack support in the existing record.

a. Petitioner first suggests that the name of respondent's juice must include the percentage of pomegranate and blueberry juices because the "proportion" of those juices "has a material bearing on price or consumer acceptance" and because "the labeling or the appearance of the food may otherwise create an erroneous impression that" those juices are "present in an amount greater than is actually the case." Br. 51-52 (quoting 21 C.F.R. 102.5(b)). Petitioner's reliance on Section 102.5(b) is misplaced.

That provision sets forth "[g]eneral principles" to "govern[] the [FDA's] establishment of a common or usual name for a food under Subpart B." 37 Fed. Reg. 12,327 (June 22, 1972); see 39 Fed. Reg. 20,908 (June 14, 1974); 21 C.F.R. 102.5(d) ("common or usual name of a food may be established by * * * regulation in subpart B"). Once FDA establishes a common or usual name in Subpart B, however, that specific naming regulation controls. See 21 C.F.R. 102.5(b) ("The following requirements shall apply unless modified by a specific regulation in subpart B of this part.").

FDA did precisely that with respect to multiple-juice beverages. See 58 Fed. Reg. at 2919 (Section 102.33 was adopted pursuant to "the basic principles for common or usual names in [Section] 102.5."). The agency provided two different ways to indicate that the named juices are not predominant. One expressly cross-references the requirements of Section 102.5(b), 21 C.F.R. 102.33(d)(2); the other (quite consciously) does not, 21 C.F.R. 102.33(d)(1). See 58 Fed. Reg. at 2920 (explaining, after discussing Section 102.5(b), that FDA "decided not to require percentage declaration[s]" if the name complies with 21 C.F.R. 102.33(d)(1)). That should be the end of the matter. See *PLIVA, Inc.* v. *Mensing*, 131 S. Ct. 2567, 2575 & n.3 (2011) ("The FDA's views are 'controlling unless plainly erroneous or inconsistent with the regulation[s]' or there is any other reason to doubt that they reflect the FDA's fair and considered judgment.") (brackets in original) (quoting *Auer* v. *Robbins*, 519 U.S. 452, 461 (1997)).

b. Petitioner also suggests (Br. 49-51) that respondent may not be able to rely on Section 102.33(d)(1) because respondent's product may not contain enough pomegranate or blueberry juice to independently characterize it. Petitioner does not point to anything in the record to support that suggestion; rather, petitioner rests on what it asserts is respondent's "telling admission that its product contains so little pomegranate and blueberry juice that those juices do *not* independently characterize the product." Br. 50. Petitioner's argument conflates two different regulations. A juice manufacturer can rely on Subsection (d)(1) so long as the "named juice is present as a flavor or flavoring." 21 C.F.R. 102.33(d)(1); see 58 Fed. Reg. at 2921. But a juice can be "present as a flavor or flavoring" under 21 C.F.R.

102.33(d)(1) and still be insufficient to "*independently* characterize the food" under 21 C.F.R. 101.22(i)(1)(i) (emphasis added). Because the record does not appear to answer the relevant question (*i.e.*, whether pomegranate and blueberry juices in respondent's product are present as flavors or flavoring), there may be an unresolved factual dispute for the lower courts to address on remand. Cf. U.S. Cert. Amicus Br. 21-22 (noting other ambiguities in the record).[8]

B. Petitioner's Lanham Act Challenge To Aspects Of Respondent's Juice Label That Are Not Specifically Required or Authorized By The FDCA Or FDA Regulations Is Not Precluded

Petitioner's Lanham Act claim is not limited to the name of respondent's juice. Petitioner also argues, for example, that respondent's juice label is misleading because of "how [respondent] presents the words 'Pomegranate Blueberry' and 'Flavored Blend of 5 Juices' on the product's label." Pet. App. 10a; see Pet. Br. 2, 10, 17, 47. Nothing in the FDCA or its implementing regulations affirmatively authorizes that labeling decision or embodies a determination by FDA that it is not misleading. Petitioner therefore should be permitted to pursue that aspect of its claim and others that the FDCA and FDA regulations do not specifically address.

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[8] In its amicus brief at the certiorari stage of this case (at 17), the government stated that the court of appeals "was correct to recognize that FDA's regulations preclude a Lanham Act challenge to the common name of respondent's juice." That statement was based on the understanding at that time that the parties did not "seriously contest" (*ibid.*) either the name's compliance with 21 C.F.R. 102.33 or the relevant facts.

1. The FDCA and its implementing regulations do not occupy the field of juice labeling

The court of appeals' decision that petitioner's Lanham Act claim was barred in its entirety rested on faulty reasoning. In the court's view, Congress had "entrust-[ed] matters of juice beverage labeling to the FDA"; the FDA had "comprehensive[ly] regulat[ed]" that "labeling"; and petitioner's claim could not proceed "[o]ut of respect for th[at] statutory and regulatory scheme." Pet. App. 12a. The court's analysis parallels that used in "so-called field pre-emption" cases, where "the scope of a [federal] statute indicates that Congress intended federal law to occupy a field exclusively." *Kurns* v. *Railroad Friction Prods. Corp.*, 132 S. Ct. 1261, 1266 (2012) (brackets in original) (quoting *Freightliner Corp.* v. *Myrick*, 514 U.S. 280, 287 (1995)).[9] That approach is inappropriate here.

To be sure, FDA has authority to regulate in the area, it has exercised that authority to some extent, and it could adopt further regulations if it saw fit. But neither the authority to regulate nor the exercise of that authority in some respects is sufficient to exclude another federal statute from that field. Cf. *English* v. *General Elec. Co.*, 496 U.S. 72, 87 (1990) ("the mere existence of a federal regulatory or enforcement scheme," even a particularly detailed one, "does not by itself imply pre-emption of state remedies"); *Geier*, 529 U.S. at 884 ("[T]he Court has looked for a specific statement of pre-emptive intent where it is claimed that the mere 'volume and complexi-

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[9] Although federal-state implied preemption principles do not control the inquiry into whether "two [federal] statutes are capable of co-existence," *J.E.M.*, 534 U.S. at 143 (citation omitted), they may assist the inquiry because they are calculated to identify laws that cannot co-exist.

ty' of agency regulations demonstrate an implicit intent to displace *all* state law in a particular area.") (citation omitted). To hold otherwise would be "tantamount to saying that whenever a federal agency decides to step into a field, its regulations will be exclusive." *Hillsborough Cnty.* v. *Automated Med. Labs., Inc.*, 471 U.S. 707, 717 (1985).

Congress did not intend the FDCA or its implementing regulations to occupy the field of juice labeling to the exclusion of other federal laws. Under 21 U.S.C. 343-1(a), a State is forbidden from "directly or indirectly" establishing any requirement "that is not identical" to certain requirements under the FDCA. 21 U.S.C. 343-1(a); see 21 C.F.R. 100.1(c)(4). Not all misbranding requirements are included; 21 U.S.C. 343(a)(1), for example, is not one of the enumerated provisions. States can petition FDA to exempt a non-identical state requirement from preemption. 21 U.S.C. 343-1(b); see 21 C.F.R. 100.1. And States can at times directly enforce certain requirements of the FDCA and its implementing regulations. 21 U.S.C. 337(b); see 21 C.F.R. 100.2. That arrangement thus permits some state unfair-competition claims and bars others. It is counterintuitive to conclude that Congress intended a total displacement of a federal remedy but only a partial displacement of state remedies of a similar nature, given that the express preemption provision was designed to promote "[n]ational[ly] uniform" labeling, 21 U.S.C. 343-1.[10]

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[10] There is also little reason to think Congress intended to preclude federal Lanham Act claims to the same extent state-law claims are expressly preempted. Congress limited the express preemption provision to non-identical requirements under *state* law, which suggests that Congress did not deem co-extensive preclusion of other *federal* law necessary to achieve national

Moreover, nothing in FDA's regulations or the preambles to those regulations suggests that FDA has marked the metes and bounds of all possible misleading material on juice labels, or that its authority must be deemed exclusive even as to matters the agency has not yet addressed. To the contrary, the preamble to the final juice-labeling regulations makes clear that even when a manufacturer complies with 21 C.F.R. 102.33, there remains considerable potential for particular labels to prove misleading. For example, although 21 C.F.R. 102.33(b) permits the characterizing juice to be declared first even if "it is not the most predominant juice," FDA cautioned that "this provision does not relieve the manufacturer of the obligation to label the product in a truthful and nonmisleading manner." 58 Fed. Reg. at 2920; see also, *e.g.*, *id.* at 2922 ("[FDA] will determine on a case-by-case basis whether a vignette is misleading because it is not consistent with other label information or for other reasons."); *FDA Guide* 12.

2. None of the other grounds identified by the courts below supports categorical preclusion

The other reasons articulated by the lower courts for finding the labeling aspects of petitioner's Lanham Act claim precluded are also without merit.

First, the courts below relied on a "line of cases" holding that a Lanham Act claim cannot proceed if the court "would be required to interpret and then apply [the

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uniformity. See Pet. Br. 29; *id.* at 29-31 (arguing Congress was "well aware that the Lanham Act applied to misleading food labels when it decided to displace only state-law labeling requirements"). Accordingly, even if some of petitioner's state-law claims were expressly preempted (a question that is currently pending before the court of appeals, see note 4, *supra*), that would not resolve the question presented here.

FDCA's] statutory or regulatory provisions." Pet. App. 50a-51a (citation omitted); see *id.* at 11a; *Schering-Plough Healthcare Prods., Inc.* v. *Schwarz Pharma, Inc.*, 586 F.3d 500, 505-509 (7th Cir. 2009). Such considerations—which mirror those underlying the doctrine of primary jurisdiction, see *Reiter* v. *Cooper*, 507 U.S. 258, 268-269 (1993)—lack force here. The application of primary-jurisdiction-like principles presupposes that the parties may "apply to the [agency] for a ruling." *Id.* at 268 n.3 (citation omitted). But FDA does not accept formal petitions to take discretionary enforcement action (see 21 C.F.R. 10.30(k)), and its decision whether to initiate an enforcement action would not be subject to judicial review (see *Heckler* v. *Chaney*, 470 U.S. 821, 837-838 (1985)). Petitioner could petition FDA to revise its labeling regulations for juice mixtures (21 U.S.C. 371(e)(1)(B); 21 C.F.R. 102.19(a)), but that would not itself redress petitioner's competitive injury.

The courts, moreover, are capable of interpreting the FDCA and FDA's food-labeling regulations, with appropriate deference to FDA's interpretation. Indeed, that is a task courts must perform to determine whether a state-law claim is expressly preempted or to adjudicate an "identical" state-law claim. See 21 U.S.C. 343-1(a); 21 C.F.R. 100.1(c)(4); cf. *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431, 453 (2005) (remanding to determine whether state-law labeling requirements were "equivalent" to federal statutory and regulatory misbranding standards under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*).[11]

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[11] To the extent FDA disagrees with a court's interpretation of an ambiguous FDCA provision or regulation, the agency can exercise its interpretive discretion through subsequent rulemaking

Second, and relatedly, the district court noted the need to "tread carefully," lest private parties use the Lanham Act to do indirectly what they cannot do directly—*i.e.*, enforce the FDCA and its implementing regulations. Pet. App. 50a; cf. *Cottrell, Ltd.* v. *Biotrol Int'l, Inc.*, 191 F.3d 1248, 1255 (10th Cir. 1999) (plaintiff "must not be permitted to bring a FIFRA claim dressed up as a Lanham Act claim"). That reasoning has no application here. Petitioner does not seek to prove its Lanham Act claim by showing that respondent's juice label violates the FDCA or FDA regulations; rather, it seeks to show that the label bears a misrepresentation independently made actionable by the Lanham Act. Respondent's preclusion *defense* injects FDCA compliance questions into the case, but that does not make this a backdoor private enforcement action.

Third, both courts below allowed the *absence* of a specific regulation to bar petitioner's claim in its entirety. The court of appeals, for example, noted that "the FDA has not (so far as we can tell) required that all words in a juice blend's name appear on the label in the same size or that words hew to some other standard that [petitioner] might have us impose." Pet. App. 10a. The district court, for its part, faulted petitioner for failing to show that the juice's common or usual name "*must* appear on one single line, *must* be in one font, or *must* be centrally located on the Juice's bottle." *Id.* at 63a (emphases added). That turns preclusion analysis on its head. There is no indication that FDA affirmatively "*deci[ded]* not to impose the requirements urged by [petitioner]." *Id.* at 12a. And the fact that FDA could have (but did not)

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or guidance. See *National Cable & Telecomms. Ass'n* v. *Brand X Internet Servs.*, 545 U.S. 967, 982-983 (2005).

adopt such regulations is an insufficient basis on which to conclude that the two federal statutes cannot coexist.[12]

Certainly, the FDCA touches on label presentation issues by providing that a food is misbranded if required label material (such as a juice mixture's common name) "is not prominently placed [on the label] with such conspicuousness * * * as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase." 21 U.S.C. 343(f). The regulations, in turn, set forth certain ways in which label material "may lack that prominence and conspicuousness." 21 C.F.R. 101.15(a); see 21 C.F.R. 101.2(c), 101.3(d). The FDA, however, has not adopted absolute or relative type-size requirements for every word in a juice's name. Compare 21 C.F.R. 102.33(d)(2) and (g)(1), 102.5(b)(2) (specifying type-size and other presentation standards for percentage declarations and the words "from concentrate"), with 21 C.F.R. 102.33(c) and (d) (not specifying any type-size or other presentation standards for words like "blend" or "flavored").[13]

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[12] The absence of an FDA enforcement action against respondent is similarly inconsequential. FDA does not have a process for approving particular juice labels, and its failure to initiate an enforcement action cannot be construed as implicit approval. See *Chaney*, 470 U.S. at 831; *Altria Grp., Inc.* v. *Good*, 555 U.S. 70, 89 (2008) ("agency nonenforcement of a federal statute is not the same as a policy of approval") (citing *Sprietsma* v. *Mercury Marine*, 537 U.S. 51 (2002)).

[13] Indeed, FDA's response to the frequently asked question, "[w]hat type sizes must be used in naming juices," referred only to 21 C.F.R. 102.5(b)(2), 102.33(d) and (g) (governing juice-percentage declarations and the words "from concentrate"). *FDA Guide* 10. And when asked whether "the entire common or usual name of a juice beverage [must] be in one place and in a single type-size," FDA responded that "[t]he entire common or usual

In addition, the FDA has made clear that information on a food label may be insufficiently prominent or conspicuous, or misleading, for "reasons" "other" than those specifically enumerated. See 21 C.F.R. 101.15(a); p. 26, *supra* (expressly cautioning manufacturers naming their products in accordance with 21 C.F.R. 102.33 about the potential for their labels to still mislead); note 7, *supra* (discussing warning letter). A suit under Section 43(a) of the Lanham Act successfully challenging material on a label as inconspicuous would tend to *reinforce*, not undo, the statutory and regulatory requirements. Cf. *Bates*, 544 U.S. at 450 ("Private remedies that enforce federal misbranding requirements would seem to aid, rather than hinder, the functioning of FIFRA.").

3. No statutory or regulatory provision specifically requires or authorizes the other features of the label challenged by petitioner

The court of appeals did not identify any statutory or regulatory provision requiring or affirmatively authorizing respondent to present the juice's common or usual name (or other matter) on the label in the manner that it appears.[14] Respondent, however, now contends (Supp. Cert. Br. 3) that 21 C.F.R. 101.22(i)(1)(i) specifically addresses "the font-size issue," that its juice label com-

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name must be in one place" and, again, noted the type-size requirements for "from concentrate" juices. *Id.* at 11.

[14] To the extent petitioner challenges the fruit vignette as misleading (Br. 52; but see Pet. App. 10a (suggesting that argument was not "meaningfully" pursued on appeal)), nothing in the FDCA or its implementing regulations precludes that claim. The district court relied on the preamble to the final rule (*id.* at 65a-69a), but FDA specifically considered whether to formally regulate the content of such vignettes and ultimately opted for a case-by-case assessment. See p. 26, *supra*.

plies with that regulation, and that any Lanham Act challenge to its juice label is thereby precluded. Respondent is incorrect for three reasons.

First, the provisions of 21 C.F.R. 101.22(i) apply to juice labeling only to the extent they are "pertinent." 56 Fed. Reg. at 30,462. Subparagraph (1)(i), on which respondent relies, explains how to declare the existence of a characterizing flavor when the food contains natural flavors, but not the ingredient itself or not enough of the ingredient to "independently characterize the food." 21 C.F.R. 101.22(i)(1)(i); see 21 C.F.R. 101.22(a)(3) (defining "natural flavor"); 21 C.F.R. 101.22(i) (defining "characterizing flavor"). In those circumstances, the "name of the food" must be "accompanied by the common or usual name of the characterizing flavor," which must be "immediately followed by the word flavored in letters not less than one-half the height of the letters in the name of the characterizing flavor." 21 C.F.R. 101.22(i)(1)(i). For example, the designation "lemon flavored cake" would be appropriate for "cake" (the name of the food) that is represented as "lemon" (the characterizing flavor) and that contains lemon oils and an insufficient quantity of lemon juice to independently flavor the food ("flavored").

That provision has no logical application here. Even if respondent's juice contains natural pomegranate and blueberry *flavors* and not enough pomegranate or blueberry *juice* to independently characterize the product (a factual question not resolved by the courts below and on which the government is not in a position to opine), its common or usual name *already* declares that the juice is pomegranate blueberry "flavored." That is required by 21 C.F.R. 102.33(d), because pomegranate and blueberry are not the predominant juices but are (presumably) "present as a flavor of flavoring" (cf. pp. 22-23, *supra*),

and because respondent opted not to declare the percentage of each of those juices. In those circumstances, having the phrase "pomegranate and blueberry flavored" stated again to "accompan[y]" the "name of the food" would be at best duplicative and at worst confusing. See *PLIVA*, 131 S. Ct. at 2575 (deferring to FDA's interpretation of its own regulations even though plaintiffs offered other ways to interpret them); 58 Fed. Reg. at 2920 (noting that Sections 101.22(i) and 102.33 are both "intended to ensure that the label communicates essential information to consumers").[15]

Second, the two federal statutory schemes can comfortably coexist unless FDA's food-labeling regulations specifically permit (or require) the allegedly misleading material. In promulgating 21 C.F.R. 102.33, FDA did not decide whether any absolute or relative type-size of the word "flavored" would (or would not) be misleading in the context of a fruit-juice label where the named juices were present only as a flavor and where the predominant juices were not named. See p. 29, *supra* (not-

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[15] That does not mean that 21 C.F.R. 101.22(i) is inapplicable to respondent's juice label in its entirety. Section 101.22(i)(1)(iii), for example, applies to foods that contain both a characterizing flavor from the product whose flavor is simulated (*e.g.*, natural flavors from lemon for lemon cake) and other natural flavor which simulates, resembles, or reinforces the characterizing flavor (*e.g.*, natural oils from other citrus fruits). If respondent's juice contains other natural flavors that simulate, resemble, or reinforce the pomegranate or blueberry flavor, the label would have to include the words "with other natural flavor." 21 C.F.R. 101.22(i)(1)(iii). Those words would have to "immediately follow[]" "the name of the food * * * in letters not less than one-half the height of the letters used in the name of the characterizing flavor." *Ibid.*

ing that FDA *did* make that sort of determination with respect to other aspects of fruit-juice labels).

Third, Section 101.22(i)(1)(i) sets forth a type-size requirement only for the word "flavored." It does not specify a type-size for the words "Blend Of 5 Juices." See 21 C.F.R. 102.33(c) (no discussion of type-size). It does not address placement of "Flavored Blend Of 5 Juices" on a line below "Blueberry" and two lines below "Pomegranate." And it does not address any other aspect of respondent's juice label. Accordingly, even if Section 101.22(i)(1)(i) applies, and even if respondent's juice label complies with the type-size requirements contained therein, petitioner's Lanham Act claim would not be barred in its entirety.

CONCLUSION

The judgment of the court of appeals should be vacated and the case remanded for further proceedings.

Respectfully submitted.

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MARCH 2014

APPENDIX

1. 15 U.S.C. 1125(a) provides in pertinent part:

False designations of origin, false descriptions, and dilution forbidden

(a) Civil action

(1) Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which—

(A) is likely to cause confusion, or to cause mistake, or to deceive as to the affiliation, connection, or association of such person with another person, or as to the origin, sponsorship, or approval of his or her goods, services, or commercial activities by another person, or

(B) in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities,

shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

* * * * *

2. 21 U.S.C. 337 provides:

Proceedings in name of United States; provision as to subpoenas

(a) Except as provided in subsection (b) of this section, all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.

(b)(1) A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 341, 343(b), 343(c), 343(d), 343(e), 343(f), 343(g), 343(h), 343(i), 343(k), 343(q), or 343(r) of this title if the food that is the subject of the proceedings is located in the State.

(2) No proceeding may be commenced by a State under paragraph (1)—

(A) before 30 days after the State has given notice to the Secretary that the State intends to bring such proceeding,

(B) before 90 days after the State has given notice to the Secretary of such intent if the Secretary has, within such 30 days, commenced an informal or formal enforcement action pertaining to the food which would be the subject of such proceeding, or

(C) if the Secretary is diligently prosecuting a proceeding in court pertaining to such food, has set-

tled such proceeding, or has settled the informal or formal enforcement action pertaining to such food.

In any court proceeding described in subparagraph (C), a State may intervene as a matter of right.

3. 21 U.S.C. 341 provides:

Definitions and standards for food

Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, or reasonable standards of fill of container. No definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocadoes, cantaloupes, citrus fruits, and melons. In prescribing any standard of fill of container, the Secretary shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food and to need for the necessary packing and protective material. In the prescribing of any standard of quality for any canned fruit or canned vegetable, consideration shall be given and due allowance made for the differing characteristics of the several varieties of such fruit or vegetable. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty

and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. Any definition and standard of identity prescribed by the Secretary for avocadoes, cantaloupes, citrus fruits, or melons shall relate only to maturity and to the effects of freezing.

4. 21 U.S.C. 343 provides in pertinent part:

Misbranded food

A food shall be deemed to be misbranded—

(a) False or misleading label

If (1) its labeling is false or misleading in any particular, * * *

* * * * *

(f) Prominence of information on label

If any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

* * * * *

(i) Label where no representation as to definition and standard of identity

Unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient and if the food purports to be a beverage containing vegetable or fruit juice, a statement with appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice contained in the food; except that spices, flavorings, and colors not required to be certified under section 379e(c) of this title[1] unless sold as spices, flavorings, or such colors, may be designated as spices, flavorings, and colorings without naming each. To the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

5. 21 U.S.C. 343-1 provides:

National uniform nutrition labeling

(a) Except as provided in subsection (b) of this section, no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—

(1) any requirement for a food which is the subject of a standard of identity established under section 341

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[1] So in original. Probably should be followed by a comma.

of this title that is not identical to such standard of identity or that is not identical to the requirement of section 343(g) of this title, except that this paragraph does not apply to a standard of identity of a State or political subdivision of a State for maple syrup that is of the type required by sections 341 and 343(g) of this title,

(2) any requirement for the labeling of food of the type required by section 343(c), 343(e), 343(i)(2), 343(w), or 343(x) of this title that is not identical to the requirement of such section, except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 343(c) of this title and that is applicable to maple syrup,

(3) any requirement for the labeling of food of the type required by section 343(b), 343(d), 343(f), 343(h), 343(i)(1), or 343(k) of this title that is not identical to the requirement of such section, except that this paragraph does not apply to a requirement of a State or political subdivision of a State that is of the type required by section 343(h)(1) of this title and that is applicable to maple syrup,

(4) any requirement for nutrition labeling of food that is not identical to the requirement of section 343(q) of this title, except that this paragraph does not apply to food that is offered for sale in a restaurant or similar retail food establishment that is not part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership of the locations) and offering for sale sub-

stantially the same menu items unless such restaurant or similar retail food establishment complies with the voluntary provision of nutrition information requirements under section 343(q)(5)(H)(ix) of this title, or

(5) any requirement respecting any claim of the type described in section 343(r)(1) of this title made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title, except a requirement respecting a claim made in the label or labeling of food which is exempt under section 343(r)(5)(B) of this title.

Paragraph (3) shall take effect in accordance with section 6(b) of the Nutrition Labeling and Education Act of 1990.

(b) Upon petition of a State or a political subdivision of a State, the Secretary may exempt from subsection (a) of this section, under such conditions as may be prescribed by regulation, any State or local requirement that—

(1) would not cause any food to be in violation of any applicable requirement under Federal law,

(2) would not unduly burden interstate commerce, and

(3) is designed to address a particular need for information which need is not met by the requirements of the sections referred to in subsection (a) of this section.

6. 21 U.S.C. 371 provides in pertinent part:

Regulations and hearings

(a) Authority to promulgate regulations

The authority to promulgate regulations for the efficient enforcement of this chapter, except as otherwise provided in this section, is vested in the Secretary.

* * * * *

(e) Procedure for establishment

(1) Any action for the issuance, amendment, or repeal of any regulation under section 343(j), 344(a), 346, 351(b), or 352(d) or (h) of this title, and any action for the amendment or repeal of any definition and standard of identity under section 341 of this title for any dairy product (including products regulated under parts 131, 133 and 135 of title 21, Code of Federal Regulations) shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2), the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

7. 21 C.F.R. 101.2(c) provides in pertinent part:

Information panel of package form food.

* * * * *

(c) All information appearing on the principal display panel or the information panel pursuant to this section shall appear prominently and conspicuously, but in no case may the letters and/or numbers be less than one-sixteenth inch in height unless an exemption pursuant to paragraph (f) of this section is established. The requirements for conspicuousness and legibility shall include the specifications of §§101.105(h) (1) and (2) and 101.15.

* * * * *

8. 21 C.F.R. 101.3 provides in pertinent part:

Identity labeling of food in packaged form.

(a) The principal display panel of a food in package form shall bear as one of its principal features a statement of the identity of the commodity.

(b) Such statement of identity shall be in terms of:

(1) The name now or hereafter specified in or required by any applicable Federal law or regulation; or, in the absence thereof,

(2) The common or usual name of the food; or, in the absence thereof,

(3) An appropriately descriptive term, or when the nature of the food is obvious, a fanciful name commonly used by the public for such food.

* * * * *

(d) This statement of identity shall be presented in bold type on the principal display panel, shall be in a size reasonably related to the most prominent printed matter on such panel, and shall be in lines generally parallel to the base on which the package rests as it is designed to be displayed.

9. 21 C.F.R. 101.15(a) provides:

Food; prominence of required statements.

(a) A word, statement, or other information required by or under authority of the act to appear on the label may lack that prominence and conspicuousness required by section 403(f) of the act by reason (among other reasons) of:

(1) The failure of such word, statement, or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;

(2) The failure of such word, statement, or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

(3) The failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;

(4) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;

(5) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device; or

(6) Smallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter.

10. 21 C.F.R. 101.22 provides in pertinent part:

Foods; labeling of spices, flavorings, colorings and chemical preservatives.

* * * * *

(a)(3) The term *natural flavor* or *natural flavoring* means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional. Natural flavors include the natu-

ral essence or extractives obtained from plants listed in §§182.10, 182.20, 182.40, and 182.50 and part 184 of this chapter, and the substances listed in §172.510 of this chapter.

* * * * *

(i) If the label, labeling, or advertising of a food makes any direct or indirect representations with respect to the primary recognizable flavor(s), by word, vignette, e.g., depiction of a fruit, or other means, or if for any other reason the manufacturer or distributor of a food wishes to designate the type of flavor in the food other than through the statement of ingredients, such flavor shall be considered the characterizing flavor and shall be declared in the following way:

(1) If the food contains no artificial flavor which simulates, resembles or reinforces the characterizing flavor, the name of the food on the principal display panel or panels of the label shall be accompanied by the common or usual name of the characterizing flavor, e.g., "vanilla", in letters not less than one-half the height of the letters used in the name of the food, except that:

(i) If the food is one that is commonly expected to contain a characterizing food ingredient, e.g., strawberries in "strawberry shortcake", and the food contains natural flavor derived from such ingredient and an amount of characterizing ingredient insufficient to independently characterize the food, or the food contains no such ingredient, the name of the characterizing flavor may be immediately preceded by the word "natural" and shall be immediately followed by the word "flavored" in letters not less than one-half the height of the letters in

the name of the characterizing flavor, e.g., "natural strawberry flavored shortcake," or "strawberry flavored shortcake".

(ii) If none of the natural flavor used in the food is derived from the product whose flavor is simulated, the food in which the flavor is used shall be labeled either with the flavor of the product from which the flavor is derived or as "artificially flavored."

(iii) If the food contains both a characterizing flavor from the product whose flavor is simulated and other natural flavor which simulates, resembles or reinforces the characterizing flavor, the food shall be labeled in accordance with the introductory text and paragraph (i)(1)(i) of this section and the name of the food shall be immediately followed by the words "with other natural flavor" in letters not less than one-half the height of the letters used in the name of the characterizing flavor.

11. 21 C.F.R. 102.5 provides:

General principles.

(a) The common or usual name of a food, which may be a coined term, shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food or its characterizing properties or ingredients. The name shall be uniform among all identical or similar products and may not be confusingly similar to the name of any other food that is not reasonably encompassed within the same name. Each class or subclass of food shall be given its own common or usual name that states,

in clear terms, what it is in a way that distinguishes it from different foods.

(b) The common or usual name of a food shall include the percentage(s) of any characterizing ingredient(s) or component(s) when the proportion of such ingredient(s) or component(s) in the food has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present in an amount greater than is actually the case. The following requirements shall apply unless modified by a specific regulation in subpart B of this part.

(1) The percentage of a characterizing ingredient or component shall be declared on the basis of its quantity in the finished product (i.e., weight/weight in the case of solids, or volume/volume in the case of liquids).

(2) The percentage of a characterizing ingredient or component shall be declared by the words "containing (or contains) ___ percent (or %) ___ " or "___ percent (or %) ___" with the first blank filled in with the percentage expressed as a whole number not greater than the actual percentage of the ingredient or component named and the second blank filled in with the common or usual name of the ingredient or component. The word "containing" (or "contains"), when used, shall appear on a line immediately below the part of the common or usual name of the food required by paragraph (a) of this section. For each characterizing ingredient or component, the words "___ percent or %) ___" shall appear following or directly below the word "containing" (or contains), or directly below the part of the common or usual name of the food

required by paragraph (a) of this section when the word "containing" (or contains) is not used, in easily legible boldface print or type in distinct contrast to other printed or graphic matter, and in a height not less than the larger of the following alternatives:

(i) Not less than one-sixteenth inch in height on packages having a principal display panel with an area of 5 square inches or less and not less than one-eighth inch in height if the area of the principal display panel is greater than 5 square inches; or

(ii) Not less than one-half the height of the largest type appearing in the part of the common or usual name of the food required by paragraph (a) of this section.

(c) The common or usual name of a food shall include a statement of the presence or absence of any characterizing ingredient(s) or component(s) and/or the need for the user to add any characterizing ingredient(s) or component(s) when the presence or absence of such ingredient(s) or component(s) in the food has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present when it is not, and consumers may otherwise be misled about the presence or absence of the ingredient(s) or component(s) in the food. The following requirements shall apply unless modified by a specific regulation in subpart B of this part.

(1) The presence or absence of a characterizing ingredient or component shall be declared by the words "containing (or contains) ___" or "containing (or contains) no ___" or "no ___" or "does not contain ___", with the

blank being filled in with the common or usual name of the ingredient or component.

(2) The need for the user of a food to add any characterizing ingredient(s) or component(s) shall be declared by an appropriate informative statement.

(3) The statement(s) required under paragraph (c)(1) and/or (2) of this section shall appear following or directly below the part of the common or usual name of the food required by paragraphs (a) and (b) of this section, in easily legible boldface print or type in distinct contrast to other printed or graphic matter, and in a height not less than the larger of the alternatives established under paragraphs (b)(2) (i) and (ii) of this section.

(d) A common or usual name of a food may be established by common usage or by establishment of a regulation in subpart B of this part, in part 104 of this chapter, in a standard of identity, or in other regulations in this chapter.

12. 21 C.F.R. 102.33 provides:

Beverages that contain fruit or vegetable juice.

(a) For a carbonated or noncarbonated beverage that contains less than 100 percent and more than 0 percent fruit or vegetable juice, the common or usual name shall be a descriptive name that meets the requirements of §102.5(a) and, if the common or usual name uses the word "juice," shall include a qualifying term such as "beverage," "cocktail," or "drink" appropriate to advise the consumer that the product is less than 100 percent juice

(e.g., "diluted grape juice beverage" or "grape juice drink").

(b) If the product is a diluted multiple-juice beverage or blend of single-strength juices and names, other than in the ingredient statement, more than one juice, then the names of those juices, except in the ingredient statement, must be in descending order of predominance by volume unless the name specifically shows that the juice with the represented flavor is used as a flavor (e.g., raspberry-flavored apple and pear juice drink). In accordance with §101.22(i)(1)(iii) of this chapter, the presence of added natural flavors is not required to be declared in the name of the beverage unless the declared juices alone do not characterize the product before the addition of the added flavors.

(c) If a diluted multiple-juice beverage or blend of single-strength juices contains a juice that is named or implied on the label or labeling other than in the ingredient statement (represented juice), and also contains a juice other than the named or implied juice (nonrepresented juice), then the common or usual name for the product shall indicate that the represented juice is not the only juice present (e.g., "Apple blend; apple juice in a blend of two other fruit juices.")

(d) In a diluted multiple-juice beverage or blend of single-strength juices where one or more, but not all, of the juices are named on the label other than in the ingredient statement, and where the named juice is not the predominant juice, the common or usual name for the product shall:

(1) Indicate that the named juice is present as a flavor or flavoring (e.g., "Raspcranberry"; raspberry and cranberry flavored juice drink); or

(2) Include the amount of the named juice, declared in a 5- percent range (e.g., Raspcranberry; raspberry and cranberry juice beverage, 10- to 15-percent cranberry juice and 3- to 8-percent raspberry juice). The 5-percent range, when used, shall be declared in the manner set forth in §102.5(b)(2).

(e) The common or usual name of a juice that has been modified shall include a description of the exact nature of the modification (e.g., "acid-reduced cranberry juice," "deflavored, decolored grape juice").

(f) If the product is a beverage that contains a juice whose color, taste, or other organoleptic properties have been modified to the extent that the original juice is no longer recognizable at the time processing is complete, or if its nutrient profile has been diminished to a level below the normal nutrient range for the juice, then the source fruits or vegetables from which the modified juice was derived may not be depicted on the label by vignette or other pictorial representation.

(g)(1) If one or more juices in a juice beverage is made from concentrate, the name of the juice must include a term indicating that fact, such as "from concentrate," or "reconstituted." Such terms must be included in the name of each individual juice or it may be stated once adjacent to the product name so that it applies to all the juices, (e.g., "cherry juice (from concentrate) in a blend of two other juices" or "cherry juice in a blend of 2 other juices (from concentrate)"). The term shall be in a

type size no less than one-half the height of the letters in the name of the juice.

(2) If the juice is 100 percent single species juice consisting of juice directly expressed from a fruit or vegetable whose Brix level has been raised by the addition of juice concentrate from the same fruit or vegetable, the name of the juice need not include a statement that the juice is from concentrate. However, if water is added to this 100 percent juice mixture to adjust the Brix level, the product shall be labeled with the term "from concentrate" or "reconstituted."

AMICUS CURIAE BRIEF

RECORD
AND
BRIEFS

Supreme Court, U.S.
FILED
MAR - 3 2014
OFFICE OF THE CLERK

No. 12-761

In the Supreme Court of the United States

POM WONDERFUL LLC,

Petitioner,

v.

THE COCA-COLA COMPANY,

Respondent.

ON WRIT OF CERTIORARI
TO THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

BRIEF OF *AMICI CURIAE* STATES OF ALASKA, HAWAII, INDIANA, MAINE, MASSACHUSETTS, MISSOURI, NEVADA, NEW HAMPSHIRE, OREGON, AND TENNESSEE IN SUPPORT OF PETITIONER

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QUESTION PRESENTED

Whether the court of appeals erred in holding that a private party cannot bring a Lanham Act claim challenging a product label regulated under the Food, Drug, and Cosmetic Act (FDCA).

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INTEREST OF *AMICI CURIAE*

The amici States take no position on the merits of petitioner Pom's underlying Lanham Act claim against Coca-Cola, nor do they suggest that Pom is itself beyond reproach from a consumer protection standpoint. *See, e.g., Pom Wonderful LLC v. Federal Trade Comm'n*, No. 13-1060 (D.C. Cir.) (pending petition for review of Federal Trade Commission false advertising action against Pom). But the amici States disagree with the apparent conclusion of the Ninth Circuit that even assuming Coca-Cola's juice labeling and marketing is misleading to consumers, the only entity that can do anything about it is the Food and Drug Administration (FDA). This holding implicates two important state interests.

First, the amici States have a strong interest in protecting consumers from deception and businesses from unfair competition. To that end, the amici States have a long history of exercising their traditional police powers to enact laws protecting citizens from unfair and deceptive business practices. These laws cover a wide range of commercial activity ranging from advertising to product safety and labeling and are enforced both through public actions by state attorneys general and through private rights of action. Federal laws that complement these state consumer protection laws—like the FDCA, the Federal Trade Commission Act, and the Lanham Act—help further the state interest in comprehensive enforcement. By creating a private right of action for those harmed by deceptive business practices, the federal Lanham Act allows private parties to supplement the efforts of the amici States and federal authorities to combat such practices. The amici

States therefore have an interest in ensuring that this federal remedy remains available.

Second, the amici States have a direct interest in how the Court analyzes the relationship between the FDCA and FDA regulations and other laws, particularly if the Court accepts Pom's invitation to draw on federal–state preemption principles and *Wyeth v. Levine*, 555 U.S. 555 (2009). Pet. Br. 16-17, 24-25, 28, 32-42. As separate sovereigns, the amici States want to ensure that their state laws—including consumer protection laws—remain effective when not expressly preempted, and that courts do not lightly infer that one law implicitly overrides another when both can be given full effect.

INTRODUCTION AND SUMMARY OF ARGUMENT

The Ninth Circuit erred in concluding that, even if Coca-Cola's "Pomegranate Blueberry" juice labeling and marketing misleads consumers, only the FDA can take corrective action. Pet. App. 11a [679 F.3d at 1177] ("If the FDA believes that more should be done to prevent deception, or that Coca-Cola's label misleads consumers, it can act. But, under our precedent, for a court to act when the FDA has not—despite regulating extensively in this area—would risk undercutting the FDA's expert judgments and authority.") FDA action need not, and should not, be the only available option to combat deceptive conduct, especially given the agency's limited resources and other priorities. The FDCA and FDA regulations leave room for a Lanham Act claim challenging aspects of a label that are not mandatory. Courts should not be so quick to find that one law implicitly cancels out another where, as here, the

two can coexist and work in tandem to further complementary goals.

Although this case involves an asserted conflict between federal laws, rather than between federal and state law, both Pom and the United States draw an analogy to federal–state implied preemption principles. Pet. Br. 32-42; U.S. Cert. Br. 10. These principles are not directly applicable here, and federal displacement of state law in an area of traditional state authority implicates federalism concerns not implicated in this case. Nonetheless, as the United States notes, federal–state implied preemption principles "are calculated to identify laws that cannot co-exist." U.S. Cert. Br. 10. Applying these principles to this case thus helps demonstrate that the FDCA and the Lanham Act can indeed coexist and both have full effect.

First, drawing an analogy to "field" preemption demonstrates that the FDCA does not "occupy the field" of food and drink labeling to the exclusion of all other laws. Rather, the FDCA explicitly allows other mechanisms such as state law to operate. In light of the long history of States' enforcement of consumer protection laws that touch on food and drink labeling and advertising, the Ninth Circuit's apparent conclusion that the FDA alone must police this entire field is both novel and extreme.

Second, drawing an analogy to "conflict" preemption demonstrates that Pom's Lanham Act claim can readily coexist with the FDCA. In preemption cases, this Court has held that a state law impliedly conflicts with a federal law, and therefore is displaced, if it is impossible to comply with both laws or the state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."

Hines v. Davidowitz, 312 U.S. 52, 67 (1941). Neither type of conflict is present here. A manufacturer can both comply with FDA's labeling requirements *and* refrain from misleading consumers in ways that create Lanham Act liability. And recognizing a concurrent Lanham Act obligation not to mislead does not pose an obstacle to the health, safety, and consumer protection purposes underlying the FDCA. On the contrary, allowing the Lanham Act and the FDCA to operate in tandem to protect consumers is more consistent with congressional objectives than leaving businesses free to use their labeling flexibility under the FDCA to mislead consumers and harm competitors with impunity.

Because Pom's Lanham Act claim can coexist with—and complement—the FDCA and the FDA's juice labeling regulations, the judgment of the Ninth Circuit should be reversed.

ARGUMENT

I. Implied preemption principles, although not controlling, help demonstrate that the Lanham Act and the FDCA can coexist.

This case does not raise a potential conflict between state and federal law, but rather a potential conflict between two federal laws. Applying an analogy to federal–state preemption cases nonetheless helps demonstrate that the Lanham Act and the FDCA can easily coexist. Although this analogy is analytically useful, the amici States caution that the outcome in this case would not be dispositive in a federal–state preemption case, which would involve additional federalism considerations.

If this were a federal–state preemption case, Coca-Cola would be required to overcome the strong presumption against preemption of state law in areas traditionally regulated by the States. *Wyeth*, 555 U.S. at 565. The Court "start[s] with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947); *see also Plumley v. Massachusetts*, 155 U.S. 461, 472 (1894) ("If there be any subject over which it would seem the states ought to have plenary control, and the power to legislate in respect to which, it ought not to be supposed, was intended to be surrendered to the general government, it is the protection of the people against fraud and deception in the sale of food products."). Courts should be especially reluctant to find that federal law overrides state law in an area like consumer protection absent an express statement by Congress or a direct and unavoidable conflict between state and federal law. The presumption against preemption of state law reflects important federalism concerns that are not implicated when two federal statutes are alleged to be in conflict.

There are nonetheless some similarities between cases addressing an alleged conflict between state law and federal law and cases addressing an alleged conflict between two federal laws. In both types of cases, courts try to give effect to both laws. In federal–federal preclusion cases, courts start with the principle that two federal laws on the same subject should be given effect to the maximum extent possible. *United States v. Borden Co.*, 308 U.S. 188, 198 (1939). "Indeed 'when two statutes are capable of coexistence, it is the duty of the courts, absent a clearly expressed congressional

intention to the contrary, to regard each as effective.' . . . [T]his Court has not hesitated to give effect to two statutes that overlap, so long as each reaches some distinct cases." *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 143-144 (2001) (internal citations omitted). The preclusion and preemption analyses are also similar in that their resolution depends upon whether Congress really intended for one law to displace another. *Wyeth*, 555 U.S. at 565 ("[T]he purpose of Congress is the ultimate touchstone in every pre-emption case.") (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1995)); *see also New York Tel. Co. v. New York State Dep't of Labor*, 440 U.S. 519, 540 n.32 (1979) ("[H]owever the conflict is viewed, its ultimate resolution depends on an analysis of congressional intent.").

Thus, although this case does not call into question the preemption of state consumer protection laws—laws presumptively not preempted by the FDCA—it is nonetheless useful to borrow from federal–state preemption cases in analyzing whether the relevant provisions of the Lanham Act and the FDCA can coexist. These cases help show that no matter how one conceptualizes the alleged tension between the laws, the Court can easily give full effect to both of them.

In federal–state preemption cases, absent an express statement by Congress that it intends to preempt state law, courts rely on two general bases to find that state law is implicitly preempted. First, when Congress intends federal law to completely occupy a given field, state law in that field may be preempted. *California v. ARC America Corp.*, 490 U.S. 93, 100 (1989) (citing *Pacific Gas & Electric Co. v. State Energy Resources Conservation and Dev. Comm'n*, 461 U.S. 190, 212-13

(1983)). Second, even if Congress has not completely occupied a field, state law may be preempted to the extent it actually conflicts with federal law. Courts have recognized two subtypes of conflict preemption: "impossibility" preemption occurs when compliance with both state and federal law is impossible; and "obstacle" preemption occurs when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *ARC Am. Corp.*, 490 U.S. at 100-101 (quoting *Hines*, 312 U.S. at 67). None of these types of preemption—applied to this case by analogy—supports the conclusion that the FDCA and the Lanham Act cannot coexist here.

II. The FDA's authority over juice labeling is not so comprehensive as to "occupy the field" of food labeling and shut out complementary enforcement efforts.

Coca-Cola maintains that Congress intended the FDCA and FDA regulations to be the "exclusive body of regulation to which food and beverage labels would be subject." Br. in Opp. 14. The Ninth Circuit agreed, concluding that the FDA's authority over juice labeling is so "comprehensive" that it shuts out even claims touching on topics the regulations do not address, such as the use of different font sizes for words within a product name. Pet. App. 12a [679 F.3d at 1178]. As the United States notes, this analysis is similar to that used in federal–state "field" preemption cases. U.S. Cert. Br. 10.

Field preemption occurs "when the scope of a statute indicates that Congress intended federal law to occupy a field exclusively." *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995). But the Court long ago

established that courts should not lightly infer field preemption. "[F]ederal regulation of a field of commerce should not be deemed preemptive of state regulatory power in the absence of persuasive reasons—either that the nature of the regulated subject matter permits no other conclusion, or that the Congress has unmistakably so ordained." *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142 (1963). Consistent with that principle, this Court rarely finds implied field preemption of state law based solely on the complex or comprehensive character of federal regulation. *See Camps Newfound/Owatonna, Inc. v. Town of Harrison*, 520 U.S. 564, 617 (1997) (Thomas, J., dissenting) ("[O]ur recent cases have frequently rejected field pre-emption in the absence of statutory language expressly requiring it."); *New York Dep't of Social Services v. Dublino*, 413 U.S. 405, 415 (1973) (rejecting "the contention that pre-emption is to be inferred merely from the comprehensive character of the federal [legislation]"). Although federalism considerations make arguments against implied field preemption even stronger in federal–state preemption cases, courts should likewise be reluctant to find that one federal law implicitly shuts out all others that might operate in the same field.

The FDCA does not "occupy the field" of food and drink labeling, conferring exclusive responsibility and authority on the FDA. This is clear because state consumer protection and food labeling laws remain effective except in a few respects where expressly preempted under 21 U.S.C. §343-1.[1] In crafting §343-1,

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[1] 21 U.S.C. §343-1 provides that "no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate com-

Congress painstakingly listed each specific statutory subsection under which state law would be preempted. And even on the topics included in §343-1, state law is not preempted completely—States may enact requirements that are identical to federal requirements and may provide their own enforcement mechanisms and remedies. The carefully constructed preemption provision in §343-1 would be superfluous if the FDCA were intended to completely occupy the field of food and beverage regulation to the exclusion of all other laws.

Moreover, the Ninth Circuit's view of the law would place a considerable burden on the FDA by making it the sole regulator, police officer, judge, and jury responsible for dealing with a wide range of potential business misconduct. Under the Ninth Circuit's expansive reasoning, even if a food or drink label contains deliberate, literal falsehoods, apparently only the FDA can act to stop it. The FDA does not have the resources to police the marketplace in this way. *Cf. Wyeth*, 555 U.S. at 578 (noting the FDA's "limited resources to monitor the 11,000 drugs on the market"). Moreover, consumers and businesses injured by deception in food and drink labeling would have no remedy because, as the United States explains, the FDA "has no authority to resolve a competitor's claim of competitive injury due to a misleading label." U.S. Cert. Br. 14.

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merce" any of 14 different specified types of requirements "that is not identical to" the corresponding FDCA requirement. For example, under §343-1(2), a State may not adopt a requirement about labeling imitation foods that is not identical to the FDCA's requirement under 21 U.S.C. §343(c) that such labels "bear[], in type of uniform size and prominence, the word 'imitation' and, immediately thereafter, the name of the food imitated."

Rather than giving the FDA exclusive responsibility to police the entire field of food and drink labeling, the FDCA contemplates that multiple sources of law and enforcement mechanisms can operate in tandem to protect consumers.

III. The Lanham Act does not directly conflict with the FDA's juice labeling regulations because it is possible to comply with both.

In federal–state preemption cases, federal law overrides state law when compliance with both "is a physical impossibility." *Fla. Lime & Avocado Growers*, 373 U.S. at 142-43. By analogy here, the FDA labeling regulations might override a Lanham Act claim that sought to prohibit something the regulations require or require something the regulations prohibit.

This type of conflict preemption necessitates careful analyses of what the two purportedly conflicting laws actually require. For example, in *Wyeth* a drug manufacturer argued for "impossibility" preemption of a state tort claim on the theory that federal law prohibited it from changing its drug label and the tort claim would have required it to do so. 555 U.S. at 568. The Court declined to find impossibility preemption because it rejected the manufacturer's interpretation of federal law, holding that the manufacturer did indeed have flexibility to change its label. *Id.* at 573. By contrast, in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011)—a similar drug label case involving different federal regulations—the Court concluded that the drug manufacturer did not have flexibility to change its label and thus found impossibility preemption. *Id.* at 2578. These cases illustrate that two laws do not di-

rectly conflict when they give regulated parties flexibility to comply with both.

Here, the laws give Coca-Cola substantial flexibility. Unlike the manufacturer in *PLIVA*, Coca-Cola is free to change its juice label at any time. And Coca-Cola can vary much of the information, design, and presentation of its label without running afoul of the FDCA or any FDA regulations. Although the FDA regulations address how multi-juice beverages can be named, the regulations neither mandate the specific name Coca-Cola has chosen for its juice nor dictate every aspect of how that name is presented. *See* 21 C.F.R. §102.33. The regulations do not appear to prohibit Coca-Cola's chosen name, "Pomegranate Blueberry Flavored Blend of 5 Juices." *Id.* But the regulations also do not *require* that Coca-Cola use this particular name for this product. Nor do the regulations mandate *how* Coca-Cola presents this name in conjunction with other labeling elements and the way it uses this name it its marketing materials.

For example, the regulations neither condone nor prohibit displaying part of this name in a smaller font on the label, as Coca-Cola has chosen to do.[2] Nor

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[2] Coca-Cola asserts that it has complied with a regulation requiring that the words "Flavored Blend of 5 Juices" appear in a font that is at least half the size of the words "Pomegranate Blueberry." Resp. Supp. 3 (citing 21 C.F.R. §101.22(i)(1)(i)). But the regulation Coca-Cola cites is inapposite because it has to do with the font size for required label information other than the product name—it does not speak to the questionable practice of using different font sizes *within* the product name in a manner that obscures the actual name. The FDA commentary makes clear that the requirement in §101.33(d)(1) that the word "flavored" appear in the product name is separate from the requirement in §101.22(i) that flavors be declared on the label in a certain way.

do they mandate the line break Coca-Cola has chosen to insert in the middle of the name, which makes it less likely that a consumer would realize that the word "Flavored" should be read together with the words "Pomegranate Blueberry" as a compound modifier for the noun "Blend." The result of Coca-Cola's voluntary formatting choices—together with its voluntary selection of a vignette dominated by a large pomegranate—is that a consumer may perceive the product name to be "Pomegranate Blueberry," conveying the impression that the product contains more than trace amounts of these juices.

A conflict between the Lanham Act and the FDCA might exist if Pom's claim challenged a specific labeling element that is actually *required* by the FDA regulations. For example, a hypothetical Lanham Act claim alleging that declaring that a juice is "from concentrate" is somehow misleading might be precluded by the regulation explicitly requiring that declaration. *See* 21 C.F.R. §102.33(g). But a Lanham Act claim challenging the many voluntary aspects of a label that includes a "from concentrate" declaration—including the manner in which the required declaration is displayed relative to other labeling elements—would not conflict with any regulations. The fact that a business must include certain information on its label does not insulate from challenge its voluntary choices about how to present that information.

See 58 Fed. Reg. 2897-01, 2920 (Jan. 6, 1993) ("[B]oth §§101.22 and 102.33 are intended to ensure that the label communicates essential information to consumers. . . . One type of information informs the consumer when flavoring substances have been added to the product. The other type describes other aspects of the basic nature of the product.").

Pom's Lanham Act complaint creates no conflict because it challenges only the *voluntary* labeling choices Coca-Cola has made, alleging that Coca-Cola's label contains "many misleading elements not required by federal or state regulation." First Am. Compl. ¶ 20. The FDCA and FDA regulations leave room for this kind of challenge because they do not exhaustively cover every aspect of labeling. Manufacturers retain substantial freedom to vary many elements of their labels, just as the manufacturer in *Wyeth* had the freedom to change its drug label. 555 U.S. at 568. And wherever manufacturers have this freedom to maneuver, the Lanham Act can—without creating a direct conflict—task them with the responsibility not to use their freedom in ways that mislead consumers.

Not only does the FDCA give manufacturers labeling flexibility, but the Lanham Act does as well. A Lanham Act judgment that Coca-Cola's label is misleading might require Coca-Cola to change and clarify its label, but Coca-Cola would have flexibility to decide how best to do so. Such a judgment would not require Coca-Cola to change any specific label element that is required by the FDCA or regulations. In *Wyeth*, the Court noted that a tort judgment finding a drug warning label inadequate did not "mandate a particular replacement warning"; rather, the manufacturer could strengthen its warning in "any number of ways." 555 U.S. at 565. Likewise here, if a Lanham Act claim against Coca-Cola's label were to succeed, Coca-Cola could redesign its label in "any number of ways" to make it less misleading. Unlike the manufacturer in *PLIVA*, Coca-Cola would not have to do anything that is prohibited by the FDCA or FDA regulations to revise its label in response to a Lanham Act judgment.

Coca-Cola asserts (Br. in Opp. 10-11) that the more specific provision—the FDA's multi-juice labeling regulation—must trump the more general one—the Lanham Act duty not to mislead consumers. But neither provision needs to "trump" the other where, as here, the two can coexist. Subjecting Coca-Cola's *voluntary* labeling and marketing choices to a Lanham Act challenge creates no direct conflict with any requirements of the FDA regulations.

IV. Lanham Act claims do not pose an "obstacle" to any congressional objective because enforcing an ongoing duty not to mislead consumers complements and supports the FDCA.

A state law that does not directly conflict with a federal law may nonetheless be held preempted if it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines*, 312 U.S. at 67. Coca-Cola makes an analogous argument here, maintaining that Pom's Lanham Act claim is precluded because it poses an obstacle to congressional purposes. That argument is without merit.

Although the presumption against preemption that applies in federal–state cases does not apply here, the Court should still give effect to both the FDCA and the Lanham Act if possible. *See Morton v. Mancari*, 417 U.S. 535, 551 (1974) ("The courts are not at liberty to pick and choose among congressional enactments, and when two statutes are capable of co-existence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective."). Like the presumption against preemption, this principle weighs strongly against finding that Lanham

Act claims are disallowed in the absence of a direct conflict. So too does the fact that the FDCA expressly preempts some specifically identified state laws, but includes no similar provision expressly ousting Lanham Act claims or equivalent state law claims. 21 U.S.C. § 343-1. Congress's inclusion of an express provision excluding some laws suggests that Congress did not intend to exclude other laws that it did not mention. *See Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 517 (1992) ("Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted.").

More generally, the Court has cautioned that a federal–state "obstacle" preemption analysis "does not justify a 'freewheeling judicial inquiry into whether a state statute is in tension with federal objectives'" because such an inquiry would intrude on congressional prerogatives. *Chamber of Commerce of U.S. v. Whiting*, 131 S. Ct. 1968, 1985 (2011) (quoting *Gade v. National Solid Wastes Management Ass'n*, 505 U.S. 88, 111 (1992) (Kennedy, J., concurring in part and concurring in judgment)). Similarly here, to avoid intruding on congressional prerogatives, the Court should avoid a "freewheeling judicial inquiry" into the various policy objectives that might arguably be obstructed if the Lanham Act is given full effect. Both the Lanham Act and the FDCA should be given full effect absent a clear and overwhelming contrary purpose. No such contrary purpose exists.

At the most basic level, the Lanham Act's prohibition on using "false or misleading" descriptions or representations in connection with goods complements, rather than obstructs, the FDCA, because the FDCA likewise prohibits food and drink labels that are "false

or misleading in any particular." *See* 15 U.S.C. §1125(a); 21 U.S.C. §343(a). To be sure, the FDA regulations impose various additional, more specific labeling requirements. *See* 21 C.F.R. §102.33. But these specific regulatory requirements neither replace the statutory obligation not to mislead consumers nor redefine the word "misleading." A label can comply with specific requirements—such as containing the words "from concentrate"—and nonetheless still be "misleading," as that word is commonly understood. Because the FDA regulations do not replace or redefine the FDCA statutory obligation not to mislead in 21 U.S.C. §343(a), they also need not supplant the separate, but complementary, Lanham Act statutory obligation not to mislead in 15 U.S.C. §1125(a), which creates a private cause of action for injured competitors. The Court will better harmonize the statutes by holding that manufacturers have *both* a Lanham Act obligation not to mislead consumers *and* an obligation to comply with the FDA's specific labeling requirements—rather than that they are free to use the flexibility granted by the FDCA to mislead consumers with impunity.

The FDA recognized that its multi-juice labeling regulations would not replace the manufacturers' obligation not to mislead. For example, in its 1993 Final Rule, the FDA noted that although it had decided not to prohibit beverage names like Coca-Cola's that begin by listing non-predominant juices, the underlying obligation not to mislead consumers would remain:

> The name of the characterizing juice may . . . be declared first although it is not the most predominant juice. However, . . . this provision does not relieve the manu-

> facturer of the obligation to label the product in a truthful and nonmisleading manner. [58 Fed. Reg. 2897-01, 2920 (Jan. 6, 1993).]

The FDA cautioned that "beverage labels are clearly misleading if they misrepresent the contribution of one or more individual juices to the nature of the product," but also recognized that "there are several ways in which a multiple-juice beverage can be appropriately labeled." In short, the FDA concluded that rigid, across-the-board regulatory prescriptions are not always warranted, *id.* at 2919, and that it need not craft regulations exhaustively addressing every way in which a label might mislead consumers. Just as the Court recognized in *Wyeth* that drug manufacturers, rather than the FDA, bear responsibility for the content of their labels at all times, food and drink manufacturers likewise bear an ongoing responsibility to ensure that their own labels are not misleading. 555 U.S. at 570-71.

The multi-juice labeling regulations thus represent only the FDA's judgment that certain minimum requirements should be imposed on all beverages and will make labels clearer and more informative in general. An FDA decision not to resolve a labeling issue with an across-the-board requirement does not constitute a judgment that the issue could never lead to a misleading label in a specific case. *Cf. Sprietsma v. Mercury Marine, a Div. of Brunswick Corp.*, 537 U.S. 51, 65-68 (2002) (rejecting the position that the Coast Guard's decision not to adopt a propeller guard regulation for boats represented a federal policy against propeller guards that would preempt a state tort suit alleging that a particular boat should have had a pro-

peller guard). For this reason, the fact that the regulations allow multi-juice beverage manufacturers to use the names of non-predominant juices (while remaining silent on Coca-Cola's formatting choices) does not mean that the FDA has determined that labels like Coca-Cola's cannot be misleading.

Nor do the gaps in the FDA's juice labeling regulations reflect a policy choice to keep those gaps open. Because the gaps are not themselves a policy choice, Lanham Act claims operating within the gaps pose no obstacle to any congressional objective. By contrast, in *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000), the Court observed that a federal agency had deliberately provided auto manufacturers with a range of different safety device choices in order to "lower costs, overcome technical safety problems, encourage technological development, and win widespread consumer acceptance." *Id.* at 875. The Court held that restricting those choices by requiring a specific safety device—an airbag—would have posed an obstacle to the deliberate policy decision to give manufacturers a range of choices. *Id.* at 886. Here, by contrast, the FDA regulations do not deliberately provide juice manufacturers with a range of labeling options for policy reasons that would be undermined if another law limited the options. No identifiable congressional policy is compromised if Coca-Cola is forced to revise and clarify its juice label in response to a Lanham Act claim. The FDCA and FDA regulations provide manufacturers with flexibility not for flexibility's sake—as in *Geier*—but because it would be unworkable to exhaustively dictate required labels for every food and drink product. *Cf. Williamson v. Mazda Motor of Am., Inc.*, 131 S. Ct. 1131, 1137 (2011) ("Like the regulation in *Geier*, the regulation here leaves the manufacturer with a

choice. And, like the tort suit in *Geier*, the tort suit here would restrict that choice. But unlike *Geier*, we do not believe here that choice is a significant regulatory objective."); *Sprietsma*, 537 U.S. at 67-68 (distinguishing *Geier*).

Moreover, a Lanham Act claim would not second-guess any FDA determination because the FDA plainly has not, as Coca-Cola contends, approved Coca-Cola's label as "not misleading." Br. in Opp. 3, 7. Congress could have—but did not—create a scheme under which the FDA would have the responsibility to examine and pre-approve individual juice labels as "not misleading" before they can be used in the marketplace. As the United States explains, the FDA "does not approve juice labels, and its failure to initiate an enforcement action cannot be construed as such an approval." U.S. Cert. Br. 16. The FDA has many duties and enforcement priorities, and the fact that it has not actively prevented Coca-Cola from using this label—one out of many thousands in the marketplace—does not constitute a considered judgment that the label is acceptable, much less that it is unassailable. Because juice labels enter the marketplace without approval and are not closely monitored by the FDA, recognizing other means of policing their content—like private Lanham Act claims—helps protect consumers.

In fact, even if Congress *had* created a juice label pre-approval process and the FDA *had* approved Coca-Cola's label, a Lanham Act claim still would not necessarily be precluded. In *Wyeth*, this Court recognized that a tort claim challenging a drug label could coexist with the FDCA even though the FDA had examined and pre-approved the label. 555 U.S. at 558. The Court disagreed that recognizing the state tort

claim would pose an obstacle to "Congress's purpose to entrust an expert agency to make drug labeling decisions that strike a balance between competing objectives." *Id.* at 574.

The argument that private claims would upset the FDA's "precise balancing" carried more force in *Wyeth*—where it failed—than it does here. *Id.* at 575. *Wyeth* involved the context of drug regulation, which requires the FDA to use its expert scientific judgment and consider the important competing objectives of drug safety and effectiveness. The Court nonetheless rejected the position that "the agency must be presumed to have performed a precise balancing of risks and benefits," leaving no room for additional requirements. *Id.* Here, the FDA's juice labeling regulations do not even arguably involve any "precise balancing" of important competing objectives that could conceivably shut out other laws. The juice labeling regulations may roughly balance a desire for labeling clarity against a desire not to create heavy labeling burdens, but this balance is not so central to the FDCA that it should be deemed inviolate. Like the federal law in *Wyeth*, the juice labeling regulations create a regulatory "floor," not a "ceiling," and no policy balance is compromised by requiring more.

Coca-Cola contends that "lay judges and juries" lack the necessary expertise to figure out what does and does not mislead consumers in the context of food and drink labeling. Br. in Opp. 17. But "false" and "misleading" are not technical terms that can only be applied through the expertise of a federal agency; they are concepts well suited to a common-sense assessment. Judges and juries are fully capable of deciding claims of misleading labeling, false advertising, and

unfair competition. *See Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 451 (2005) (upholding power of juries to apply the misbranding provision of the Federal Insecticide, Fungicide, and Rodenticide Act). Indeed, it is a simpler task than evaluating the failure-to-warn claim about a drug label that this Court permitted to go forward in *Wyeth*. 555 U.S. at 558.

Far from creating an obstacle, law suits establishing that specific food and drink labels are misleading consumers—such as Lanham Act suits based on consumer survey data—would both help inform the FDA in crafting new regulations and support its enforcement efforts. As the Court explained in *Wyeth*, "[s]tate tort suits uncover unknown . . . hazards and provide incentives for . . . manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information." 555 U.S. at 579; *see also Bates*, 544 U.S. at 451 (explaining that private state law remedies "would seem to aid, rather than hinder" functioning of federal statute).

Nor would Lanham Act challenges to product labels create an undesirable patchwork of different labeling requirements; they would simply enforce the ongoing obligation not to use the flexibility granted by the FDA regulations to mislead consumers. Coca-Cola's emphasis on Congress's desire for labeling uniformity elevates one purported sub-goal of the FDCA over its larger purpose—to protect consumer health and safety with clear and accurate product labeling. Congress did want some uniformity, and thus acted to prevent States from enacting different, potentially conflicting, labeling laws about certain specific topics like nutrition facts. See 21 U.S.C. §343-1(a)(4). But this sub-goal of

the larger statutory scheme is insufficient to oust Lanham Act claims absent a direct conflict, given the presumption in favor of giving both laws full effect.

Allowing Lanham Act challenges to food and drink labels is more consistent with the FDCA's health, safety, and consumer protection goals than leaving businesses free to design their labels to mislead consumers unless the FDA intervenes. Lanham Act claims thus pose no "obstacle" to the accomplishment of congressional objectives.

CONCLUSION

The judgment of the Ninth Circuit should be reversed.

Respectfully submitted,

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Dated: MARCH 2014

AMICUS CURIAE BRIEF

RECORD AND BRIEFS

Supreme Court, U.S.
FILED
APR - 2 2014
OFFICE OF THE CLERK
SUPREME COURT, U.S.

No. 12-761

In the
Supreme Court of the United States

POM WONDERFUL LLC,

Petitioner,

v.

THE COCA-COLA COMPANY,

Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF *AMICUS CURIAE* AMERICAN BEVERAGE ASSOCIATION IN SUPPORT OF RESPONDENT

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April 2, 2014

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INTEREST OF *AMICUS CURIAE* [1]

Amicus curiae the American Beverage Association ("ABA") is the trade association representing the broad spectrum of companies that manufacture and distribute non-alcoholic beverages in the United States, including regular and diet soft drinks, bottled water and water beverages, 100-percent juice and juice drinks, sports drinks, energy drinks, and ready-to-drink teas. Founded in 1919, the ABA represents hundreds of beverage producers, distributors, bottlers, franchise companies, and support industries. ABA's members employ more than 233,000 workers nationwide, generate U.S. sales in excess of $140 billion per year, and participate in food safety initiatives as they apply to and impact beverages. ABA has a substantial interest in ensuring that any regulations to which its members are subject are applied in a clear, efficient, and nationally uniform manner. To this end, ABA regularly represents its member companies in federal rulemaking proceedings and litigation when the issues presented will broadly affect the industry.

Pursuant to its express statutory authority under the Federal Food, Drug, and Cosmetic Act ("FDCA") and Nutritional Labeling and Education Act ("NLEA"), the Food and Drug Administration ("FDA") has promulgated comprehensive regulations regarding the labeling of multi-juice beverages. The

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[1] This brief was not written in whole or in part by counsel for any party, and no person or entity other than *amici* and their counsel has made a monetary contribution to the preparation and submission of this brief. The parties have consented to the filing of this brief.

FDA has provided clear guidance about how to comply with the regulations regarding misbranding, and has given beverage manufacturers multiple options for how to prepare a compliant label.

POM's Lanham Act claims would fundamentally upend this regulatory regime. The FDA's expert policy judgments about how products can be labeled in a non-misleading manner would be rendered largely meaningless if beverage manufacturers could be subject to Lanham Act claims for "misleading" labels even where those labels fully comply with the FDA's regulations. Worse still, Lanham Act claims brought by competitors would eviscerate the uniformity and regulatory certainty that the FDA's regulations were designed to provide. ABA and its members thus have a powerful interest in ensuring that the FDA's regulations remain the exclusive means through which beverage labels are regulated.

SUMMARY OF ARGUMENT

I. POM's core argument is that the name or label of a multi-juice beverage is "misleading" unless it prominently displays the constituent juices *by volume*. But the expert agency that Congress tasked with overseeing food labels has reached a different conclusion. Based on several unique characteristics of the beverage industry, the FDA concluded that it is not misleading for manufacturers to use labels that focus on the *flavor* of a multi-juice beverage rather than its ingredients by volume.

That conclusion was well-grounded in both the agency's extensive rulemaking record and common sense. Some fruit and vegetable juices have much stronger flavors than others, and a small amount of a

distinctly-flavored juice can go a long way in altering the taste of a blended beverage. Moreover, although POM seems to favor a rule that requires prominent disclosure of the exact percentages of each ingredient in a multi-juice blend, the FDA has rejected that *exact* proposal as unworkable. There is often some degree of variation in the makeup of multi-juice blends due to changes in the price or availability of ingredients, and beverage companies must have the flexibility to make those changes without having to constantly re-design their labels. A full-disclosure-at-all-costs rule would also threaten intellectual property rights by forcing companies to divulge beverage recipes that constitute some of their most valuable trade secrets.

POM's theory of Lanham Act liability would severely undermine the FDA's expert judgments and uniform national standards regarding beverage labeling. And beverage companies would be deprived of clear guidance about how to design labels that comply with the law. Rather than being subject to one set of comprehensive national standards, beverage companies would be subject to the whims of juries across the country under an amorphous totality-of-the-circumstances test. It is complicated and expensive to change the label on a nationally-distributed product, and POM's theory of Lanham Act liability would ensure that manufacturers *never* have certainty that their labels comply with the law.

II. When Congress enacted the FDCA in 1938, it made clear that only the government—not private parties—may enforce the prohibitions on misbranding. The FDCA's lack of a private right of

action was not an accident or oversight. It was instead a reasoned policy decision that expert regulators should decide when and how to enforce the FDCA. Congress recognized that the FDA should have broad discretion to choose when to exercise its enforcement authority, and to address issues one step at a time through a deliberative rulemaking process. The FDA's enforcement discretion and expert judgment would be undermined if private parties could bring their own claims challenging a label as "misleading" even when the FDA has made a reasoned decision that it is not.

POM's Lanham Act claims are just the most recent in a long line of attempts by plaintiffs to evade Congress' prohibition on private suits to enforce the FDCA. Although POM asserts that its Lanham Act claims are wholly distinct from the requirements of the FDCA, there is no question that its claims address matters within the heartland of the FDA's exclusive authority—namely, whether the manner in which a beverage label depicts ingredients is "misleading." POM's Lanham Act claims will interfere with the FDA's discretion and enforcement authority every bit as much as a private claim brought directly under the FDCA. If POM is dissatisfied with how the FDA has regulated multi-juice beverages, the proper remedy is to ask the FDA to change its rules, not to make an end-run around the statutory prohibition on private claims to enforce the FDCA.

III. Finally, although this case is cloaked in issues of statutory interpretation, it is still, at bottom, a case about restricting speech that

implicates the First Amendment. A product's name and label have a significant expressive component, as they are one of the most important ways in which a company communicates with its customers.

The FDA's comprehensive labeling regulations certainly burden protected expression, but they also contain several important safeguards to ensure that no more speech is chilled than necessary to advance the FDA's goals of preventing deception and promoting informed consumer choice. For example, the regulations provide clear and specific guidance about what companies must do in order to comply with the law, and the FDCA's ban on private suits prevents over-enforcement in borderline cases. The Lanham Act, in contrast, contains no such safeguards. Lanham Act claims are evaluated under an amorphous totality-of-the-circumstances test, and plaintiffs (*i.e.*, competitors) have no incentive whatsoever to exercise restraint in bringing such claims.

When it comes to expressive speech protected by the First Amendment, one layer of comprehensive and detailed regulation is more than enough. Given that beverage manufacturers' speech is already carefully regulated by a federal agency, it simply goes too far to then subject that speech to *another* level of regulation through case-by-case Lanham Act claims by any private plaintiff with a beef. There is a far greater risk to First Amendment freedoms when any private plaintiff can attack commercial speech, as opposed to allowing a single regulator to address labeling subject to uniform rules and without private enforcement. POM's approach poses a serious risk of

chilling protected expression, and the Lanham Act should be interpreted to avoid that constitutionally dubious result.

ARGUMENT

I. POM's Lanham Act Claims Would Severely Undermine The Flexible National Standards That Are Central To The FDA's Regulatory Regime.

Throughout its brief, POM suggests that the FDA's detailed and comprehensive labeling regulations merely establish a "floor" that can be supplemented on a case-by-case basis through Lanham Act suits. Those arguments misconstrue the FDA's regulations and wholly ignore the unique features of the beverage industry that were central to the FDA's policy decisions. The FDA's regulations were designed to ensure that consumers have all the information they need to make informed choices, while also providing beverage manufacturers with significant *flexibility* in naming and labeling their products. POM's Lanham Act claims would upend that scheme and allow labeling decisions to be made on an *ad hoc* basis by juries, rather than on a uniform national basis by the expert administrative agency.

A. Any Rules Regarding Naming and Labeling of Juices Must Take into Account the Unique Features of the Food and Beverage Industry.

The FDA's regulations regarding the naming and labeling of multi-juice blends were carefully crafted to accommodate several unique characteristics of the beverage industry.

First, it is extremely costly and complicated for food and beverage producers to change the labels on their products. Labels are one of the key ways in which a company interacts with its customers, and they are subject to exhaustive reviews within the company before being approved. Changing a label not only undermines the company's branding efforts but also poses a logistical nightmare. In order to change all of its labels at once, the company would have to recall millions of existing products, potentially resulting in a massive waste of perishable merchandise. Alternatively, the company could change the labels only for newly produced products, but that could lead to customer confusion as products with both the new label and old label are simultaneously in circulation. It is thus critical for any regulation of labels to provide clear standards for compliance that will minimize the need for costly changes.

Second, as all consumers know, some ingredients have much stronger flavors than others. A seemingly miniscule amount of jalapeño pepper can completely change the flavor of a food product. And one squeeze of lemon or lime can significantly alter the taste of a drink, even if the beverage is largely comprised of other ingredients. Beverage manufacturers offer countless products in which small amounts of distinctly-flavored juices—such as cranberry, pomegranate, blueberry, mango, and acai—are used to enhance the flavor of more "conventional" juices such as apple and grape. Relatedly, some juices are denser than others, and denser juices will typically have a stronger flavor than less-concentrated juices. Thus, there is often a substantial disconnect between

the predominant *flavors* in a beverage and the predominant *ingredients* as measured by volume.

In ABA's experience, consumers typically choose a juice product based on its characterizing flavor; unsurprisingly, taste is also a critical determinant of customer satisfaction.[2] When one ingredient is responsible for a significant portion of a beverage's flavor profile, it is entirely reasonable for the product name to prominently feature that ingredient, even if it comprises only a small percentage of the total volume. Indeed, under those circumstances, it can be *affirmatively misleading* to name a product based on its primary ingredients rather than its characterizing flavor.[3] Here, for example, if Coke had named its product "Apple-Grape Blend of Five Juices," many consumers would have been quite surprised to learn that the beverage tasted like a mix of blueberries and pomegranate and did not taste like either apple or grape juice.

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[2] *See, e.g.*, Nat'l Soft Drink Ass'n Comments at 7, Docket No. 80N-0140 (FDA Aug. 1, 1991) ("NSDA Comments") ("Consumers generally are more concerned with taste, quality, value, and total juice content than with the individual amounts of each component juice in a blend"). The National Soft Drink Association changed its name to the American Beverage Association in 2004.

[3] *See* Welch Foods Inc.'s Comments at 4, Docket No. 80N-0140 (FDA July 30, 1991) ("The flavor of a juice product is probably the single greatest determinant of product satisfaction and can only be evaluated by tasting. Consequently, the idea that the consumer can determine 'value' ... by knowing the percentage of each juice in the product is not supportable, but may, in itself cause misjudgment and confusion.").

Third, the prices and availability of fruits and vegetables can be extremely volatile. Nearly all fruits and vegetables have some degree of seasonal price variation, and prices are also affected by weather patterns, global supply and demand, and international trade conditions. As a result, beverage manufacturers often adjust the proportions of ingredients in their products in response to changes in cost or availability. And, for a company that has multiple manufacturing facilities, there may be slight variations among the products produced at different facilities. In short, it is impossible to have an entirely standardized food or beverage product, and any labeling regulations must be flexible enough to accommodate the inherent variations in such products. *See* NSDA Comments at 7 (declaration of the specific percentages of each ingredient could "deprive producers of the flexibility to make minor adjustments in component juices").

Fourth, recipes are often a food or beverage company's most valuable trade secrets. Even though the same "basic ingredients" are used in many recipes, the "combination in which those ingredients are used" and the manner in which they are prepared are routinely deemed to be trade secrets. *Peggy Lawton Kitchens, Inc. v. Hogan*, 466 N.E.2d 138, 139-40 (Mass. App. Ct. 1984); *see also Magistro v. J. Lou, Inc.*, 703 N.W.2d 887, 890-91 (Neb. 2005) (pizza dough recipes were trade secrets); *Uncle B's Bakery, Inc. v. O'Rourke*, 920 F. Supp. 1405, 1428-29 (N.D. Iowa 1996) (bagel company's "recipes, manufacturing, and packaging processes" were all trade secrets). A regulatory regime that required disclosure of the exact amount of each ingredient in a

food or beverage would jeopardize proprietary recipes and, indeed, would risk being a taking of manufacturers' intellectual property. *Cf. Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984) (applying regulatory takings doctrine to government-mandated disclosure of proprietary information). Needless to say, one does not need to look beyond the named parties to this litigation to understand the salience of this point. Perhaps the Nation's most famous secret formula would not be a secret if Respondent had to display on its label precisely what flavors went into making a Coke a Coke.

B. The FDA's Regulations Were Carefully Designed To Accommodate the Competing Interests at Stake While Providing Regulated Parties Flexibility in Labeling Juice Blends.

Based on these characteristics of the industry, the FDA made an eminently reasonable policy judgment that beverage manufacturers should have flexibility in how they name and label multi-juice blends.

The FDA has been studying the question of how to label multi-juice beverages for decades. Throughout the 1980s, the FDA initiated multiple rulemaking proceedings on this topic and considered several citizen petitions seeking specific regulations regarding multi-juice beverages. *See* 56 Fed. Reg. 30,452, 30,455 (July 2, 1991) (summarizing regulatory history). After the NLEA was enacted in 1990, the FDA again sought public comment on "how to represent accurately the contents of juice blends and diluted multiple-juice beverages containing one

or more characterizing flavors." *Id.* at 30,452; *see id.* (requesting comment on "whether the percentage of characterizing juices should be labeled"). Those proceedings resulted in a comprehensive rulemaking record that included comments from all interested stakeholders, including consumer groups, agricultural interests, beverage manufacturers, States, and individual citizens.

Several of the comments filed during the rulemaking process were strikingly similar to the arguments POM has raised in this case. For example, one commenter complained that "some juice beverages have misleading labels in that high cost/value or intense flavor juices are given greatest label prominence but are present in minor amounts." 58 Fed. Reg. 2,897, 2,900 (Jan. 6, 1993); *compare* POM Br. 2 ("every aspect of the product's appearance is tailored to convince consumers that it contains significant amounts of pomegranate and blueberry juice"). And other groups sought detailed regulation of illustrations on product labels (also known as "vignettes"), arguing that any vignette should "accurately reflect the quantity of fruit present." 58 Fed. Reg. at 2,922; *compare* POM Br. 52 (complaining that Coke's vignette "features outsized blueberries" and "prominently features a large pomegranate").

The FDA carefully considered those proposals, but ultimately rejected them as unnecessary or unworkable. As the agency explained, "it is not necessary to require that each juice in a beverage be named to ensure that the label is not [] misleading." 58 Fed. Reg. at 2,919. The "basic nature of the product can be described in various ways, *e.g.*, as a

blend of five juices, with a declaration of the name of the juice or juices that provide the characterizing flavor, as long as it is clear from the name that other juices are present." *Id.*

The FDA stated in no uncertain terms that the "name of the characterizing juice may [] be declared first *although it is not the predominant juice.*" *Id.* at 2,920 (emphasis added). That is, the agency recognized that it is entirely appropriate to name a multi-juice blend based on its "characterizing flavor," even if the characterizing juice comprises only a small percentage of the overall volume. A label that describes the characterizing juice as a "flavor"—like Coca-Cola's label here—"will inform the consumer that the juice is present in an amount sufficient to flavor the beverage but will not imply that the content of that juice is greater than is actually the case." *Id.* at 2,921.

The FDA also rejected a proposal that would have required all constituent juices in a blend to be disclosed in 1%-increments, finding that such a rule was "not practicable." *Id.* The agency emphasized that beverage producers "need to have flexibility in the formulation of the beverage to accommodate variations in raw material juices and price changes." *Id.* The FDA thus allowed beverage makers to comply with its naming rules for multi-juice blends by *either* stating that a named characterizing juice is present only as a "flavoring" *or* disclosing the amount of the named juice in a 5-percent range. *See* 21 C.F.R. § 102.33(d).

Finally, the FDA also rejected the detailed regulation of vignettes that several commentators

had sought. The agency concluded that a vignette that depicts the fruits used to flavor a multi-juice blend "would not be misleading," even if some of those juices were present only in small amounts. 58 Fed. Reg. at 2,921. The FDA also flatly rejected proposals that would have required fruits on a vignette to be "depicted in proportion to the amount of each juice present." *Id.* at 2,922. Such a rule would be too "difficult" for manufacturers to implement, and would be of little benefit to consumers. *Id.*

C. POM's Lanham Act Claims Would Disrupt the FDA's Regulatory Regime and Lead to Significant Uncertainty and Practical Problems.

If accepted by this Court, POM's theory of Lanham Act liability would fundamentally upend the FDA's regulatory regime, and would lead to serious practical problems for beverage manufacturers.

Most important, POM's Lanham Act claims would severely undermine the FDA's flexible and nationally uniform approach to beverage labeling. One of the FDA's primary goals in its misbranding regulations was to promote "national uniformity in certain aspects of food labeling, so that the food industry can market its products efficiently in all 50 States in a cost-effective manner." 58 Fed. Reg. 2,462, 2,462 (Jan. 6, 1993). The agency determined that "the net benefits from national uniformity in these aspects of the food label outweigh the loss in consumer protection that may occur" if labels are not subject to case-by-case litigation. *Id.*

POM, in contrast, argues that—in addition to the FDA's detailed regulations—every juice label is also potentially subject to an amorphous, totality-of-the-circumstances inquiry under the Lanham Act. Tellingly, POM never specifies exactly what it thinks Coke *should have done* to make its label non-misleading. At some points in its brief, POM suggests that Coke was obligated to disclose the exact percentages of each juice in its blend, an obligation specifically considered and affirmatively rejected by the FDA in its labeling rules. *Compare* 58 Fed. Reg. at 2,920 ("declaration of percentage of individual juices represented on the label is not required") *with* POM Br. 51-52 ("Coca-Cola's label does not include—or even hint at—the trivial percentage of pomegranate and blueberry juice in the product."). At other points, POM suggests that Coke should have given its product a different name or included more information on the front of the label. *See id.* at 10 ("Coca-Cola's front label does not even mention the product's overwhelmingly dominant ingredients—apple juice or grape juice—by name.").[4] And POM argues elsewhere that the vignette on the label depicting the constituent fruits should have been crafted differently by, for example, shrinking the "outsized blueberries." *Id.* at 52.

It is anyone's guess when a label rises to the level of "misleading" under POM's totality-of-the-

[4] It is unsurprising that POM limits its challenge to the front of the label, given that other FDA regulations require all ingredients to be listed "in descending order of predominance by weight" in the statement of ingredients on the back of the label. *See* 21 C.F.R. § 101.4(a)(1).

circumstances inquiry. What if the "outsized blueberries" in the vignette were shrunk to what POM deems an appropriate size? What if the statement "flavored blend of five juices" was listed in the same font as "Pomegranate Blueberry" on the front label? Or what if Coca-Cola had named its product "Blueberry/Apple/Pomegranate/Grape Juice"? POM does not even attempt to explain which aspects of the label are dispositive under its theory; it merely asserts that all of this somehow adds up to a Lanham Act violation, or at least a Lanham Act claim that a jury could sort out. And, of course, another competitor might have different theories about why the same label is "misleading."

Food and beverage companies sell their products into a nationwide marketplace. It is wholly untenable for each label to be subject to the FDA's comprehensive regulatory scheme *plus* an amorphous, totality-of-the-circumstances inquiry that will vary from court to court and will ultimately be resolved by juries that may not possess the expertise required to interpret FDA regulations. *See Schering-Plough Healthcare Prods., Inc. v. Schwarz Pharma, Inc.*, 586 F.3d 500, 509 (7th Cir. 2009) (FDA "has more experience with consumers' understanding of drug labels than judges do"). The FDA can consider labeling issues comprehensively and strike a reasonable balance among the many competing interests at stake. A jury, in contrast, will focus on a single label in isolation, while disregarding the broader policy interests that might be undermined if such labels were prohibited. *Cf. Riegel v. Medtronic*, 552 U.S. 312, 325 (2008) ("A jury ... sees only the cost

of a more dangerous design, and is not concerned with its benefits.").

Indeed, POM's theory of Lanham Act liability would effectively nullify one of the two options provided by the FDA for labeling multi-juice beverages. The regulations provide two alternatives for how a multi-juice beverage can comply with the misbranding rules, and provide clear, uniform guidance about the requirements for each alternative. *See* 21 C.F.R. § 102.33(d)(1) (manufacturer can indicate that a non-predominant juice is "present as a flavor or flavoring"); *id.* § 102.33(d)(2) (manufacturer can identify the amount of a non-predominant juice within a 5-percent range). When a juice blend has a "chara .terizing flavor," the FDA has concluded that "*it is not necessary* to require that each juice in a beverage be named to ensure that the label is not [] misleading." 58 Fed. Reg. at 2,919 (emphasis added). POM, however, argues that it *is* "misleading" under the Lanham Act to name and label a juice blend based on its characterizing flavor rather than its predominant ingredients by volume.

It is difficult to imagine a more clear-cut example of a private party seeking to second-guess and override the policy determinations of an expert agency. POM effectively seeks to use the Lanham Act to *prohibit* labels that are expressly *authorized* by the FDA's regulations. Needless to say, the choice provided by the FDA will be rendered meaningless if choosing the "wrong" option can lead to Lanham Act liability. When a federal agency has provided regulated entities with a "range of choices" for compliance with a regulation, any attempt to nullify

that choice through private tort claims stands as an obstacle to the federal policy and must yield to the agency's regulations. *Geier v. American Honda Motor Co.*, 529 U.S. 861, 874-86 (2000).

II. Congress' Express Refusal To Include A Private Right Of Action In The FDCA Must Be Given Effect.

POM asserts (at 32, 37) that it is not seeking to enforce the FDCA or the FDA's regulations, but is instead attempting to use the Lanham Act to *supplement* the FDCA. This Court should reject that maneuver for all of the reasons set forth in Coke's brief. But even if POM were merely attempting to *enforce* the requirements of the FDCA through the Lanham Act, its claims would still fail.

A. The FDCA's text and legislative history make clear that Congress intended the government, not private parties, to have exclusive responsibility for enforcing the prohibition on misbranding. Since its enactment in 1938, the FDCA has provided that "all ... proceedings for the enforcement, or to restrain violations, of this chapter *shall be by and in the name of the United States.*" 21 U.S.C. § 337(a) (emphasis added). During the debates over the FDCA, Congress considered—and rejected—a version of the bill that would have allowed a private right of action for damages. *See National Women's Health Network v. A.H. Robins Co.*, 545 F. Supp. 1177, 1179-80 (D. Mass. 1982) (summarizing legislative history).

Courts have consistently honored this congressional judgment. Thus, there is no need for courts to distinguish between the "bad old days" of implied causes of action, *see Alexander v. Sandoval*,

532 U.S. 275, 286-88 (2001), and the modern reluctance to infer such actions from congressional silence, *id.* When it comes to the FDCA, there is "no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance." *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 349 n.4 (2001).[5]

Congress granted the FDA sweeping authority to enforce the FDCA. The FDA can seek an injunction to restrain violations, 21 U.S.C. § 332, impose civil *and criminal* penalties, *id.* § 333, and seize adulterated or misbranded products, *id.* § 334.[6] Critically, however, the statute also grants the FDA authority *not* to enforce the Act to its fullest possible extent. Section 336 provides that "[n]othing in this chapter shall be construed as requiring the Secretary to report for prosecution, or for the institution of [] injunction proceedings, minor violations of this chapter whenever he believes that the public interest will be adequately served by a suitable written notice or warning." *Id.* § 336.

That is, Congress recognized that it is not necessarily in the public interest to have the FDCA

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[5] In 1990, the NLEA carved out a narrow exception to exclusive federal enforcement for suits brought by a State "*in its own name*" to enforce certain provisions of the FDCA. 21 U.S.C. § 337(b)(1) (emphasis added). But those amendments did not in any way authorize enforcement by private parties.

[6] The FDA has not hesitated to use those far-reaching powers when it deems appropriate. *See* Warren Leary, *Citing Labels, U.S. Seizes Orange Juice*, New York Times (Apr. 25, 1991) (FDA inspectors seized 2,000 cases of orange juice made from frozen concentrate that was falsely labeled as "fresh").

enforced to its fullest possible extent in all circumstances. Taken together, Sections 336 and 337 make clear that the federal government has exclusive authority to both enforce and *decline to enforce* the federal requirements regarding misbranding. *See United States v. Sullivan*, 332 U.S. 689, 694 (1948) (under Section 336, agency need not bring enforcement actions for "technical infractions of law").

For example, the FDA has concluded that a product may be labeled as "calorie free" or "zero calories" as long as it has "less than 5 calories per reference amount customarily consumed." 21 C.F.R. § 101.60(b)(1). Similarly, a "nonfat" or "fat free product" is not deemed misbranded if it has "less than 0.5 g[rams] of fat per labeled serving." *Id.* § 101.62(b)(1). Some consumers might be surprised to learn that a product labeled "fat free" actually has small amounts of fat, and class actions have been filed over equally trivial variances.[7] But the FDA concluded based on an extensive rulemaking record that the 0.5 gram threshold is "appropriate because it is the reliable limit of detection of fat in all types of foods, and thus analytically equates it to zero." 58 Fed. Reg. 2,302, 2,328 (Jan. 6, 1993). The FDA's

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[7] ConAgra Foods has been sued by class-action plaintiffs alleging that its "Parkay Spray" product—which contains small amounts of fat per serving—"is deceptively labeled, marketed and sold to ... consumers as having '0 fat' and '0 calories.'" Class Action Complaint at 1, *Allen v. ConAgra Foods, Inc.*, No. 3:13-cv-1279 (N.D. Cal. Mar. 21, 2013); *see also The Non-Fat Yogurt*, Seinfeld (NBC, Nov. 4, 1993) ("I promise you, my fellow New Yorkers, that Mayor Giuliani will do everything possible to cleanse this city of this falsified non-fat yogurt.").

enforcement discretion and expert judgment would be rendered meaningless if private parties could bring their own claims challenging a label as misleading even when the FDA has made a reasoned decision not to act.

B. Plaintiffs have been trying for decades to evade Section 337's ban on private actions to enforce the FDCA. Plaintiffs' lawyers initially tried to convince courts to invent an implied right of action for private parties to enforce the FDCA directly. But, as noted, the courts resisted any effort to infer a cause of action under the FDCA. The lower courts have uniformly held that "Congress did not intend, either expressly *or by implication*, to create a private cause of action under the FDCA." *Bailey v. Johnson*, 48 F.3d 965, 968 (6th Cir. 1995) (emphasis added); *see also PDK Labs v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997) ("no ... private right of action exists" under the FDCA"); *In re Orthopedic Bone Screw Products Liability Litig.*, 193 F.3d 781, 788 (3d Cir. 1999) ("It is well-settled ... that the FDCA creates no private right of action.").

After those theories were rejected, plaintiffs tried a variety of different maneuvers to evade the FDA's exclusive enforcement authority under Section 337. Some plaintiffs sought to evade Section 337 by cloaking their misbranding claims in state-law causes of action. Although there is some tension among the lower courts on this issue, the far better view is that such claims cannot be brought because they stand as a direct obstacle to the policy of exclusive government enforcement embodied in Section 337. It would have made no sense at all for

Congress to have prohibited private actions to enforce the FDCA while simultaneously allowing private misbranding claims to be brought under state law. A private right of action "is equally inconsistent with the federal regulatory scheme, whether the right is based in federal or state law." *National Women's Health Network*, 545 F. Supp. at 1181.

For example, in *Fraker v. KFC Corp.*, No. 06-cv-1284, 2007 WL 1296571 (S.D. Cal. Apr. 30, 2007), the court found that state-law challenges to health claims made by a fast-food company were impliedly preempted by the FDCA. As the court explained, "[t]o overlay the state law tort system over the FDCA would significantly increase the burdens on the FDA to ensure uniform enforcement of its administrative duties." *Id.* at *4. Thus, the plaintiffs' state-law claims were barred by federal law to the extent they depended on "alleged violations of the FDCA." *Id.*

Another court similarly held that "Massachusetts cannot confer on private persons the power to enforce a federal statute whose enforcement Congress left to federal administrative agencies." *Animal Legal Defense Fund Boston, Inc. v. Provimi Veal Corp.*, 626 F. Supp. 278, 283 (D. Mass. 1986). Even though the complaint was ostensibly brought under the "Massachusetts consumer protection statute," the court nonetheless found that it was "preempted by the FDCA." *Id.* That is, plaintiffs may not evade the prohibition on private actions under the FDCA through a state "statute which parallels the FDCA." *Id.*; *see also Healthpoint, Ltd. v. Ethex Corp.*, 273 F. Supp. 2d 817, 838 (W.D. Tex. 2001) (plaintiffs cannot bring claims under state law

that "involve[] all the facts and arguments to be determined in a misbranding enforcement action, matters within the sole jurisdiction of the FDA").[8]

C. POM's Lanham Act claims are just the most recent attempt to do indirectly what Section 337 bars private parties from doing directly. POM asserts (at 25-28) that its Lanham Act claims are wholly distinct from the FDCA and that its claims can "easily coexist" with the FDA's exclusive authority to enforce the FDCA. But, tellingly, POM makes no attempt to compare the *text* of the two statutes. The FDCA provides that food is impermissibly misbranded if "its labeling is false or misleading in any particular." 21 U.S.C. § 343(a)(1). Using nearly identical language, the Lanham Act prohibits a "false or misleading description of fact, or false or misleading representation of fact" in connection with the sale of goods or service. 15 U.S.C. § 1125(a)(1).

Thus, although POM is nominally seeking relief under the Lanham Act, it is also accusing a beverage company of using a "misleading" label—which is precisely the type of issue that Congress has committed to the FDA's expert discretion. POM's

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[8] *But see In re Farm Raised Salmon Cases*, 175 P.3d 1170, 1181-84 (Cal. 2008) (holding that Section 337 does not preempt private claims under state misbranding law that was "identical" to the FDCA). A pending petition for certiorari—in which this Court has called for the views of the Solicitor General—challenges a similar decision from the California Supreme Court holding that private parties could use the California unfair competition law to enforce the requirements of a federal law that did not include a private right of action for damages. *See Rose v. Bank of America*, 304 P.3d 181 (Cal. 2013), *petition for cert. filed* No. 13-662 (U.S. Nov. 27, 2013).

Lanham Act claims will interfere with the FDA's policy judgments every bit as much as private claims brought directly under the FDCA. Indeed, the enhanced remedies available under the Lanham Act—such as disgorgement of profits and recovery of attorneys' fees, *see* 15 U.S.C. § 1117—would make such claims particularly attractive to plaintiffs and particularly inconsistent with Congress' decision to assign such judgments to the expert agency.

The fact that there is some play in the joints about how a company can comply with the FDA's regulations does not mean that there is a vacuum to be filled by *ad hoc* Lanham Act claims. It instead reflects the reasoned judgment of the expert agency about how best to balance and accommodate the many competing interests at stake. Some percentage of consumers may feel "confused" or "misled" by nearly any statement a company makes about a food or beverage. Sections 336 and 337 ensure that the FDA has authority to prohibit statements that are *actually* misleading while also preventing the harm to the industry that would result from over-enforcement of labeling rules based on trivial or *de minimis* allegations of misbranding.

* * *

In sum, POM's approach would allow the Lanham Act to "stray[] too close to the exclusive enforcement domain of the FDA," and would "'usurp[] the FDA's discretionary role in the application and interpretation of its regulations.'" *Summit Technology, Inc. v. High-Line Medical Instruments*, 922 F. Supp. 299, 306 (C.D. Cal. 1996). Congress made a reasoned determination—embodied in

Sections 336 and 337 of the FDCA—that the FDA should be responsible for crafting and enforcing regulations regarding misbranding of food and beverages, and that private enforcement should play no role whatsoever in that scheme. If POM is dissatisfied with how the FDA has chosen to regulate beverage labels, this "is a problem to be addressed by the FDA and not by the courts in a Lanham Act suit." *American Home Products Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 145 (S.D.N.Y. 1987).

III. The Lanham Act Should Be Construed To Avoid The Serious First Amendment Concerns That Would Arise From Over-Regulation Of Protected Expression.

Finally, although the resolution of this case will turn largely on questions of statutory interpretation, this is still—at heart—a case about the regulation of speech that implicates important First Amendment interests. In reconciling and harmonizing the FDA's regulations and the Lanham Act, this Court should ensure that these First Amendment interests are protected, and that no more speech is chilled than necessary to serve the government's goals of preventing misbranding and promoting informed consumer choice. There is no question that the legal regime envisioned by POM would create a speaker-beware environment when it comes to beverage labels. In light of the FDA's ability to prevent misleading speech, there is no reason to adopt a rule that chills more speech than is necessary.

A. There is no question that the First Amendment applies to product names and labels. As a number of lower courts have recognized, "[p]roduct

labels, which are part of a firm's marketing plan to provide certain information to the consumer ... constitute commercial speech." *Adolph Coors Co. v. Brady*, 944 F.2d 1543, 1546 (10th Cir. 1991); *see also International Dairy Foods Ass'n v. Boggs*, 622 F.3d 628, 635 (6th Cir. 2010) ("composition claims" about a product, such as "antibiotic-free" and "pesticide-free," constitute commercial speech); *Pearson v. Shalala*, 164 F.3d 650, 655 (D.C. Cir. 1999) ("It is undisputed that FDA's restrictions on ... health claims are evaluated under the commercial speech doctrine."); *Hornell Brewing Co. v. Brady*, 819 F. Supp. 1227, 1233 (E.D.N.Y. 1993) ("The Crazy Horse Malt Liquor label is indisputably commercial speech.").

Indeed, even if product names and labels are deemed to be "commercial speech," they are still fundamentally *expressive* in nature. Product names and labels are how companies differentiate their products in a competitive marketplace and build lasting relationships with consumers. "In today's world, branding is more important than ever," as product branding "convey[s] a uniform quality, credibility, and experience."[9] A brand is "a company's face to the world," and includes "the company's name, how that name is visually expressed through a logo, and .... how the company is perceived by its customers."[10]

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[9] Scott Goodson, *Why Brand Building Is Important*, Forbes (May 27, 2012), http://www.tinyurl.com/7b5w22r.

[10] *The Importance of Branding Your New Business*, New York Times (Mar. 18, 2009), http://www.tinyurl.com/78ntbme.

For example, Ben & Jerry's is well-known among consumers for its uniquely named ice cream flavors (*e.g.*, "Cherry Garcia," "Half Baked," "John Lennon's Imagine Whirled Peace"), and its labels often contain graphics or messages about political and social issues. Other companies similarly boast on their labels that their products are "fair trade" or "sustainably grown." These product names and labels are far more than just descriptive; they are important expressions about a company's values and the image it seeks to convey to the public.

B. Given the significant expressive component of product names and labels, any regulation of this speech must not be "more extensive than is necessary" to serve the government's interests in preventing deception and allowing consumers to make informed choices. *Central Hudson Gas & Elec. Corp. v. Public Service Comm'n of New York*, 447 U.S. 557, 566 (1980). That is, any regulation of this type of speech must avoid unnecessarily chilling protected expression.

The FDA's regulations impose an exhaustive array of requirements on the names and labels of food and beverage products. The regulations provide detailed instructions about what manufacturers can name their products. *See* 21 C.F.R. §§ 102.5, 102.22-102.57. They commandeer a significant portion of product labels for government-mandated disclosures of ingredients and nutritional information. *Id.* §§ 101.1-101.5, 101.9. They restrict claims that can be made about nutrients and calorie content (*i.e.*, whether a product is "light," "low sodium," or a "good source of vitamins"). *Id.* §§ 101.54-101.69. They

provide extraordinarily detailed rules about the types of health claims that food and beverage manufacturers can make. *Id.* §§ 101.70-101.83. And an entire regulation is devoted to placing restrictions on when food and beverage companies can characterize their products as "fresh" or "frozen." *Id.* § 101.95.

Although these regulations certainly *burden* protected expression, they also contain built-in safeguards to ensure that speech is not restricted more than necessary to advance the FDA's policy goals. Most important, the FDA has minimized any potential chilling effect on protected speech by clearly specifying what a company needs to do to comply with the misbranding rules. The regulations provide a relatively clear picture of how to comply with the law, thus allowing food and beverage companies to utilize creative names or labels while still complying with the FDA's regulations.

The lack of a private right of action in the FDCA also serves First Amendment values by preventing over-enforcement of the misbranding regulations. In selecting remedies for misbranding, the FDA has broad discretion to balance the public interest against the speaker's right of free expression. For example, the FDA may issue a warning letter before bringing a formal enforcement action, or may seek to remedy alleged misbranding on a *prospective* basis only rather than seeking penalties or damages for past conduct. Because the FDA has limited resources, it also has strong incentives to act through clear regulations and carefully targeted enforcement actions. In short, the FDA is likely to restrict

protected speech only where necessary, and its enforcement actions for misbranding will be taken only in circumstances where consumers are most likely to be harmed.[11]

Lanham Act claims, in contrast, have none of the speech-protecting features of the FDA's regulations. In contrast to the FDA's clear guidance about how to comply with the misbranding regulations, Lanham Act suits are necessarily *ad hoc* and based on an amorphous totality-of-the-circumstances test. *See supra* 13-16. This Court has repeatedly emphasized that vague or imprecise laws "raise[] special First Amendment concerns because of [their] obvious chilling effect on free speech." *Reno v. ACLU*, 521 U.S. 844, 871-72 (1997); *see also Citizens United v. FEC*, 558 U.S. 310, 324 (2010) (vague laws "chill speech" because regulated parties "'must necessarily guess at [the law's] meaning'"); *Pearson*, 164 F.3d at 661 ("it must be possible for the regulated class to perceive the principles which are guiding" a regulation of speech).

Moreover, there is no check whatsoever on private parties' ability to bring Lanham Act suits challenging a competing product's name or label. *See New York Times v. Sullivan*, 376 U.S. 254, 277 (1964) (safeguards for the defendant in a government

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[11] For example, after reviewing POM's websites in January 2010, the FDA found "serious violations" of the FDCA based on POM's claims that its juices can be used to treat medical conditions ranging from heart infections to erectile dysfunction. *See* Warning Letter from Roberta C. Wagner to POM Wonderful (Feb. 23, 2010), http://www.fda.gov/iceci/enforcementactions/warningletters/ucm202785.htm.

enforcement action "are not available to the defendant in a civil action"). Companies can face years of litigation as a result of Lanham Act claims initiated by their competitors, even if the FDA would not have deemed the case worthy of an enforcement action or warning letter. The Lanham Act's relatively unconstrained private cause of action thus poses a much greater threat to First Amendment values than circumscribed government enforcement actions.

C. This Court has long held that "[a] statute must be construed, if fairly possible, so as to avoid not only the conclusion that it is unconstitutional but also *grave doubts* upon that score." *United States v. Jin Fuey Moy*, 241 U.S. 394, 401 (1916) (emphasis added); *see FCC v. Fox Television Stations*, 556 U.S. 502, 516 (2009) ("ambiguous statutory language should be construed to avoid serious constitutional doubts"). The same principles should govern how to reconcile two competing federal statutes. When one statute already addresses First Amendment-protected activity in a way that specifically foreswears the chilling effect of private causes of action, courts should err on the side of caution and the First Amendment in not allowing a duplicative private cause of action.

In the course of harmonizing the FDA's regulations and the Lanham Act, the First Amendment interests at stake should tip the balance in favor of protected speech and against Lanham Act claims. There are few, if any, other industries in which it would be acceptable for a federal regulator to tell companies how they can name and label their

products, and what adjectives they can use to describe their products. To be sure, the FDA's regulations may be justified by the important government interests in preventing deception and promoting informed consumer choice. But that does not change the fact that these regulations impose significant speaker-based and content-based restrictions on protected expression. *Cf. Sorrell v. IMS Health Inc.*, 131 S. Ct. 2653, 2662 (2011).

Given that food and beverage manufacturers' speech about their products is *already* micro-managed by the FDA in countless ways, it raises serious First Amendments concerns to then subject that FDA-authorized speech to yet another layer of regulation through *ad hoc*, totality-of-the-circumstances Lanham Act claims. Once a company clears the many hurdles imposed by the primary regulator, the restrictions on protected speech should be at an end. POM's "prophylaxis-upon-prophylaxis approach to regulating expression," *see FEC v. Wisconsin Right to Life, Inc.*, 551 U.S. 449, 479 (2007) (plurality op.), must be rejected.

In this regard, it bears emphasis that there is an obvious alternative to more speech-chilling lawsuits—more speech. If POM believes it has a superior product, it is perfectly free—subject to FDA regulations—to go to the airwaves and trumpet what makes its product a better juice. That is clearly the remedy that First Amendment values favor. The choice between more speech and more speech-chilling private actions is not a close one.

* * *

When it comes to expressive speech protected by the First Amendment, one layer of comprehensive and detailed regulation is more than enough. This Court should construe the Lanham Act to avoid the serious constitutional concerns that would arise if speech that is already exhaustively regulated by the FDA were also subject to case-by-case adjudication under the amorphous standards of the Lanham Act.

CONCLUSION

This Court should affirm the judgment of the Ninth Circuit.

Respectfully submitted,

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April 2, 2014

AMICUS CURIAE BRIEF

RECORD AND BRIEFS

No. 12-761

Supreme Court, U.S.
FILED
MAR - 3 2014
OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

POM WONDERFUL LLC,

Petitioner,

v.

THE COCA-COLA COMPANY,

Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF OF *AMICUS CURIAE* THE AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF NEITHER PARTY

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STATEMENT OF INTEREST

The American Intellectual Property Law Association ("AIPLA") is a voluntary bar association with approximately 15,000 members who are lawyers in both private and corporate practice, judges, patent agents, academics, law students, and USPTO professionals. Our members practice in a wide and diverse spectrum of intellectual property fields, including patent, trademark, copyright, and unfair competition law, as well as other fields of law affecting intellectual property. They represent owners and users of intellectual property, as well as those who litigate and prosecute before patent and trademark offices.[1]

AIPLA has no interest in any party to this litigation and has no stake in the outcome of this case, other than its interest in seeking a correct and consistent interpretation of the laws affecting intellectual property.[2]

---

1. In accordance with Supreme Court Rule 37.6, AIPLA states that this brief was not authored, in whole or in part, by counsel to a party, and that no monetary contribution to the preparation or submission of this brief was made by any person or entity other than AIPLA or its counsel. After reasonable investigation, AIPLA believes that (i) no member of its Board or *Amicus* Committee who voted to file this brief, or any attorney in the law firm or corporation of such a member, represents a party to this litigation in this matter, (ii) no representative of any party to this litigation participated in the authorship of this brief, and (iii) no one other than AIPLA, or its members who authored this brief and their law firms or employers, made a monetary contribution to the preparation or submission of this brief.

2. AIPLA sought consent to file this brief from the counsel of record for all parties, pursuant to Supreme Court Rule 37.3(a). Counsel for Petitioner and Respondent informed AIPLA of their consent by countersigned letters, and the letters have been filed with this brief.

SUMMARY OF ARGUMENT

The appellate court interpreted too broadly the potential conflict between the regulations promulgated under the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* ("FDCA") and the Nutrition Labeling and Education Act ("NLEA"), Pub. L. No. 101-535, 104 Stat. 2353 (1990), and the section of the Lanham Act providing for a private right of action for false and misleading advertising, 15 U.S.C. § 1125(a)(1). This ruling has the potential to severely undermine the ability of parties to use the Lanham Act to prevent false and misleading advertising in areas where the FDA also regulates (or has the authority to regulate) such information.

The appellate court affirmed the dismissal of Pom's false advertising claim under Section 43(a)(1) of the Lanham Act, 15 U.S.C. § 1125(a)(1), with respect to the naming and labeling of Coca-Cola's "Pomegranate Blueberry Flavored Blend of 5 Juices" product. *Pom Wonderful LLC v. The Coca-Cola Co.*, 679 F.3d 1170, 1179 (9th Cir. 2012). In its Lanham Act claim, Pom asserted that the name of the juice blend was misleading notwithstanding the fact that the naming method employed by Coca-Cola purported to follow regulations promulgated under the FDCA and the NLEA. Regulations enacted thereunder at 21 C.F.R. § 102.33(c) and (d) regulate the juice names and certain information contained on juice labels. Section 102.33(c) recognizes that a juice blend can use a juice component in its name or label even if the blend "also contains a juice other than the . . . juice" named or represented on the label. A "named" juice need "not [be] the predominant juice" by volume. 21 C.F.R. § 102.33(d). The juice in this case contained 0.3% pomegranate juice, 0.2% blueberry

juice and over 99% apple and grape juice. *Pom Wonderful*, 679 F.3d at 1172.

The court of appeals noted that the FDCA "comprehensively regulates food and beverage labeling." *Id.* at 1175. The court sought "to give as much effect to both statutes as possible, . . . to strike a balance that disrupts the two statutory schemes as little as it can." *Id.* at 1176. The court held that "[t]he naming component of Pom's claim is barred because, as best as we can tell, FDA regulations authorize the name Coca-Cola has chosen." *Id.*

The reasons given for affirmance are overly broad and are prone to misinterpretation. The court of appeals observed that, with respect to its determination, it was "primarily guided . . . not by Coca-Cola's apparent compliance with FDA regulations but by Congress's decision to entrust matters of juice beverage labeling to the FDA and by the FDA's comprehensive regulation of that labeling." 679 F.3d at 1178. It declined to disturb the FDA's "judgments" (though, in a literal sense, there was no judgment or approval of the name or label by the FDA, but instead a regulation governing them), "[o]ut of respect for the statutory and regulatory scheme." *Id.*

On this point, the court of appeals is mistaken: its determination should have been guided by Respondent's compliance with particularized FDA regulations. It is not enough to have a comprehensive set of regulations. The regulation itself must expressly allow the act complained of for there to be a conflict with the Lanham Act.

This particular case provides a compelling illustration for why the Lanham Act should be broadly applied. Petitioner claims that the inclusion of literally one teaspoon of pomegranate and blueberry juice transforms a quart of apple and grape juice into a "Pomegranate Blueberry Flavored Blend of 5 Juices." The public is not well served by this deception.

Any decision of this Court should make clear that a Lanham Act claim alleging the confusing or deceptive character of a product label, asserted for consumer protection and to prevent unfair competition, is not barred by the jurisdiction of the FDA to generally regulate the content of such labels where the particular conduct alleged is not specifically governed by express regulations, or approved by specific administrative review, even where regulatory authority for such regulations is available but unexercised. It should also confirm that a Lanham Act plaintiff may assert a false advertising claim that a label is misleading in part because it does not conform to the requirements of an FDA regulation.

ARGUMENT

I. WHERE LABELING CONDUCT IS COMPLETELY GOVERNED BY REGULATIONS THAT STATE EXPRESS REQUIREMENTS OR PROVIDE FOR AGENCY REVIEW, A LANHAM ACT CHALLENGE TO THE PROPRIETY OF FOLLOWING SUCH REGULATIONS OR RELYING ON THE AGENCY IS BARRED.

Where labeling conduct is completely governed by regulations that state express requirements or provide for agency review, a Lanham Act challenge to the propriety of following such regulations or relying on the agency is barred.

To hold otherwise would undermine the authority of the FDCA, the NLEA, and the related regulations, and the FDA's pronouncements that certain methods of naming juices are allowable when they meet the criteria established in the regulation. For example, the FDA considered it appropriate to label a drink as "flavored" by the named juice, concluding that such labeling "will adequately deal with the kinds of misleading labeling discussed in the comments from consumer groups." *Pom Wonderful LLC v. The Coca-Cola Co.*, 727 F. Supp. 2d 849, 864-865 (C.D. Cal. 2010) (citing Food Labeling; Declarations of Ingredients; Common or Usual Name for Nonstandardized Foods; Diluted Juice Beverages, 58 Fed. Reg. 2900 (Jan. 6, 1993) (to be codified at 21 C.F.R. §§ 101, 102)). If the juice otherwise complied with the regulations (such as by satisfying the juice flavoring requirements specified to permit the use of this naming method), then there should be no Lanham Act claim available to assert

that a name that meets the express requirements of the regulation is nonetheless itself a violation of the Lanham Act.

Where relief sought under the Lanham Act is not "capable of coexistence" with the FDCA, and its regulations, the Lanham Act claim should be barred. *See J. E. M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 143-144 (2001). It is the obligation of the courts to give full effect to both statutes where possible: "The courts are not at liberty to pick and choose among congressional enactments, and when two statutes are capable of co-existence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective." *Morton v. Mancari*, 417 U. S. 535, 551 (1974).

Giving full effect to the FDA regulations and the Lanham Act may not be possible with respect to certain aspects of the regulation where one federal statute expressly prohibits conduct that is expressly allowed by the other. *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861 (2000), a state law preemption case, is instructive on this point. In *Geier*, the plaintiffs brought a state tort claim against an automobile manufacturer alleging product defect and negligence in failing to install an air bag into its vehicles. In *Geier*, as in this case, there was no indication that Congress intended to preempt the field and the federal law contained a savings clause. 529 U.S. at 867-68.[3] This Court held that there was an actual conflict

3. *See* 21 U.S.C. § 343-1(a) note (1990) (Construction of Pub. L. 101-535: The statute "shall not be construed to preempt any provision of State law, unless such provision is expressly preempted" thereunder.)

with federal law that preempted the state law claims. *Id.* at 861. It found that the federal motor vehicle regulations provided manufacturers an alternative to installing air bags, including the use of automatic belts or passive interiors. A state cause of action predicated on the theory that a vehicle without an air bag installed is defectively or negligently designed would thus stand "'as an obstacle to the accomplishment and execution of' the important means-related federal objectives." *Id.* at 881-82 (quoting *Hines v. Davidowitz*, 312 U.S. 52, 67 (1940)).

A conflict between two federal statutes, or between a statute and a set of regulations duly authorized by federal statute, should be treated similarly. The conflict between them should be read narrowly, to give full effect to both, and certainly to an extent similar to that provided in the preemption cases. This is the approach taken by courts considering the potential conflict between a federal statute or regulation and the Lanham Act in cases where an agency provided express approval and or where a party complied with an express regulation.[4]

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4. *See, e.g. Cottrell, Ltd. v. Biotrol Inter., Inc.*, 191 F.3d 1248, 1254-56 (10th Cir. 1999) (rejecting Lanham Act claim "requir[ing] the court to interpret and apply regulations that are exclusively in the province of the EPA"); *Am. Home Prods. Corp. v. Johnson & Johnson*, 672 F. Supp. 135, 145 (S.D.N.Y. 1987) (holding FDA's express approval of a drug label cannot be attacked through Lanham Act claims); *VP Racing Fuels, Inc. v. Gen. Petroleum Corp.*, 673 F. Supp. 2d 1073, 1085 (E.D. Cal. 2009) (representation of octane level based on certification complying with federal Petroleum Marketing Practices Act cannot give rise to Lanham Act claim).

II. WHERE LABELING CONDUCT IS NOT COMPLETELY GOVERNED BY EXPRESS FDA REGULATIONS, SUCH CONDUCT CAN BE THE BASIS OF A LANHAM ACT CLAIM.

Where the regulations do not expressly govern product labeling, or where the FDA has not expressly reviewed the exact label at issue and passed on its acceptability with respect to those regulations, there should be room to argue that the labeling conduct constitutes advertising that is actionable under the Lanham Act. Indeed, for years courts have recognized that literally true statements can be misleading, depending on context and use. *See, e.g.*, 5 J. Thomas McCarthy, *McCarthy on Trademarks and Unfair Competition* § 27:53 (4th ed. 2013). For example, Coca-Cola's use of pomegranate and blueberry in its juice name was predicated on it "provid[ing] the characterizing flavor." *See Pom Wonderful*, 679 F.3d at 1177; Reply Brief for Petitioner on Petition for Writ of *Certiorari* at 4, *Pom Wonderful, LLC v. The Coca Cola Co.*, No. 12-761 (March 2013). A Lanham Act claim should be available to explore whether including minute amounts of pomegranate and blueberry juice supplies the characterized "flavoring" contemplated in the regulations to allow for the naming method employed. *See* 21 C.F.R. 102.33(b). In the absence of the product tasting like pomegranate and blueberry juice or containing more than a trace amount of these fruits, a plaintiff should be allowed to explore whether such labeling is misleading under the Lanham Act, regardless of the regulations.

This should also be the case for another aspect of the FDA regime governing labels; *i.e.*, determining whether the text placement and relative font size of Coca-Cola's label violate 21 U.S.C. § 343(f). That statute requires

wording on a label to be "prominently placed" so "as to render it likely to be read and understood by the ordinary consumer under customary conditions of purchase and use." *Id.*

Similarly, in this case, there is potential ambiguity as to what the juice is and what the flavoring is. The label could plausibly be read to identify the product as pomegranate juice that has blueberry flavoring, or, as Respondent is contending, it could be read to identify it as a pomegranate-and-blueberry flavored juice. The failure to use a signaling word like "and" or a hypen "Pomegranate-Blueberry Flavored" could suffice to make the label deceptive and actionable under the Lanham Act.

A Lanham Act claim alleging the confusing or deceptive character of a product label, asserted for consumer protection and to prevent unfair competition, may not be barred merely by the jurisdiction of the FDA to regulate the content of such label. Where the label is not specifically authorized by the FDCA or FDA regulations, even where regulatory authority for such regulations is available but unexercised, this Court should hold that a Lanham Act claim may proceed.

The Lanham Act provides a cause of action against false advertising, which may be directed at "any goods . . . or any container for goods." 15 U.S.C. § 1125(a)(1). In enacting the Lanham Act, Congress expressly stated its goal to protect commercial interests against particular forms of unfair competition, including false advertising. *Id.* at § 1127; *see also Two Pesos, Inc. v. Taco Cabana, Inc.*, 505 U.S. 763, 767–68 (1992). Congress intended not only to protect "the good will of" businesses, but also to "protect[] the public against spurious and falsely marked goods." S. Rep. No.

79-1333, at 3 (1946), reprinted in 1946 U.S.C.C.A.N. 1274, 1274-75; *see also* McCarthy § 27:31.

The FDA has acknowledged the limitations of its regulatory scheme. In the context of "multiple-juice beverages that name one or more but not all of the juices present" such as Respondent's, the FDA has recognized the "great potential for the label to misrepresent the contribution of the named juice to the product" under its regulations. 58 Fed. Reg. 2897-901, 2920 (Jan. 6, 1993). The availability of Lanham Act relief to redress such misrepresentations thus aligns with the FDA's purposes.

To the extent the Lanham Act can coexist with the other federal statutes, it must be given effect. *See Morton*, 417 U. S. at 550-551 (construing the potential conflict between the Equal Employment Opportunity Act of 1972 and the Indian Reorganization Act of 1934). This Court "has not hesitated to give effect to two statutes that overlap, so long as each reaches some distinct cases." *J. E. M. Ag Supply*, 534 U.S. at 144 (citation omitted). The NLEA does not purport to limit the Lanham Act, and in the nearly twenty-four years since its enactment, Congress has not deemed it necessary to do so.

The court of appeals based its improperly broad approach primarily on another recent decision in that circuit, *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919 (9th Cir. 2010): "*PhotoMedex* teaches that courts must generally prevent private parties from undermining, through private litigation, the FDA's considered judgments." *Pom Wonderful*, 679 F.3d at 1178. The court in *PhotoMedex* refused to allow a Lanham Act claim that, among other things, challenged the truth of a claim that a product was "cleared" by the FDA. *See id.* at 1176.

To the extent the *PhotoMedex* holding was based solely on the premise that the FDA retains exclusive jurisdiction over matters it regulates, it is in conflict with decisions of other appellate courts that have allowed Lanham Act claims that included assertions challenging the veracity of claims of government approval.

For example, in *N. Am. Med. Corp. v. Axiom Worldwide, Inc.*, 522 F.3d 1211 (11th Cir. 2008), the court affirmed a Lanham Act claim including an allegation that defendant falsely represented that the product was FDA approved. In doing so, the court was careful to note that the Lanham Act claim was not a collateral attack on the FDA approval process:

> "[T]he district court did not step into the FDA's shoes when it ruled that the DRX 9000 was not approved. The district court was not making a determination whether the device should be approved, it merely noted what the FDA had already determined."

Id. at 1226 n. 15; *see also Alphapharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934, 939-41 (8th Cir. 2005) (allowing Lanham Act claim asserting that a representation that the FDA had approved a drug was false and deceptive); *Cottrell, Ltd.*, 191 F.3d at 1255-56 (allowing Lanham Act claim that manufacturer misleadingly represented that it had obtained EPA clearance for a surface cleaner); *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222 (3d Cir. 1990) (Lanham Act claim concerning alleged misrepresentation of the action of a drug regulated by the FDCA).

Conversely, the court *Mylan Laboratories, Inc. v. Matkari* refused to allow a Lanham Act claim to go forward where it amounted to an indirect way to enforce the FDCA. 7 F.3d 1130, 1139 (4th Cir. 1993). In that case, the plaintiff alleged that defendants violated the Lanham Act by falsely stating or implying that their drugs had been "properly approved by the FDA" when the FDA had not done so. *Id.* According to the plaintiff, the acts of putting the drug on the market and using standard package inserts of the type used by approved drugs misled the public into believing that the drug had received FDA approval. *Id.* The defendant was not alleged to have made any affirmative statements of "FDA approval." *Id.*

The court rejected the Lanham Act claim because it would "permit Mylan to use the Lanham Act as a vehicle by which to enforce the Food, Drug, and Cosmetic Act ("FDCA") and the regulations promulgated thereunder." *Id.* This case and the others described above largely strike the right balance in giving full effect to Lanham Act claims concerning misrepresentations of government approval while preventing collateral attack on agency decisions.

The availability of Lanham Act relief with respect to areas not specifically and expressly regulated by the FDA will serve to support the aims of the FDCA and NLEA. This is especially true in light of the alignment of purpose shared by the FDCA and Lanham Act to protect consumers.[5]

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5. *Compare Mut. Pharm. Co., Inc. v Bartlett*, 133 S. Ct. 2466, 2494 (2013) (J. Sotomayor, dissenting) (recognizing "FDCA's core purpose of protecting consumers") *and U.S. v. Lane Labs-USA Inc.*, 427 F.3d 219, 226 (3d Cir. 2005)("protecting consumer health and safety is a primary purpose of the FDCA") *with* S. Rep. No.

Applying the standard urged by AIPLA will give maximum effect to the Lanham Act without impeding the reach of the FDCA and NLEA. Permitting Lanham Act unfair competition claims that do not conflict with FDA regulations poses no threat to the FDA's regulatory authority, and preserves the important rights of consumers and competitors to bring federal false advertising claims under the Lanham Act.

Because the District Court improperly dismissed Petitioner's Lanham Act claim under an improper view of the law, this case should be vacated and remanded for further proceedings.

III. A LANHAM ACT CLAIM CAN BE BASED IN PART ON LACK OF COMPLIANCE WITH FDA REGULATIONS.

Lanham Act false advertising claims can be based upon, *inter alia*, "[s]tatements that are literally true or ambiguous but which nevertheless have a tendency to mislead or deceive the consumer." *United Indus. Corp. v. Clorox Co.*, 140 F.3d 1175, 1182 (8th Cir. 1998).[6] In this respect, a misrepresentation that the government has authorized or approved of the conduct or that it complies

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79-1333, at 4-5 (1946), reprinted in 1946 U.S.C.C.A.N. 1274, 1276-77 (purpose of the Lanham Act to "protect[] the public against spurious and falsely marked goods").

6. *See also Procter & Gamble Co. v. Chesebrough-Pond's Inc.*, 747 F.2d 114, 119 (2d Cir. 1984) (in addition to blatant falsehoods, the Lanham Act "embraces 'innuendo, indirect intimations, and ambiguous suggestions' evidenced by the consuming public's misapprehension of the hard facts underlying an advertisement") (citations omitted).

with government requirements is merely a subset of the variety of misrepresentations of quality, efficacy, safety, approval, authority or affiliation that typically support a claim for unfair competition. Thus, an applicant for FDA approval may well satisfy a labeling regulation with content that is literally true, but that content could be implicitly false or deceptively misleading. A Lanham Act claim, which would not require reexamination of prior agency determinations, should be available to test the veracity or misleading nature of the statement.

Even to the extent that the FDA has specifically regulated conduct, the mere existence of such regulation should not, without more, preclude a Lanham Act suit relating to that conduct. While a private litigant should not be permitted to use the Lanham Act to collaterally attack the decisions of the FDA, or to allege conduct expressly permitted by FDA regulations is a violation, these prohibitions should not be interpreted so broadly as to prevent a Lanham Act plaintiff from pointing to a defendant's clear *non*-compliance with the FDCA as an evidentiary basis for a false advertising claim.[7]

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7. *See N. Am. Med. Corp.*, 522 F.3d at 1225-26; *Alphapharma, Inc.*, 411 F.3d at 939-41; *Cottrell, Ltd.* 191 F.3d at 1255-57; *Mut. Pharm. Co. v. Ivax Pharms., Inc.*, 459 F. Supp. 2d 925, 939 (C.D. Cal. 2006) ("In adjudging this claim the Court need not interpret and then apply any FDA regulation; instead, it need only verify whether defendants' label conforms to what the FDA has already determined is required to be listed for quinine sulfate, something which the Court can do 'without any need to interpret [and then apply] FDA regulations.'") (quoting *Summit Technology, Inc. v. High-Line Medical Instruments Co.*, 933 F. Supp. 918, 933, n.7 (C.D. Cal. 1996)).

To do so does not impinge on the FDA's authority. *See Grove Fresh Distributors, Inc. v. Flavor Fresh Foods, Inc.* 720 F. Supp. 714, 716 (N.D. Ill. 1989) (allowing Lanham Act claim based in part on non-compliance with FDA regulation). In refusing to dismiss plaintiff's Lanham Act claim, the court in *Grove Fresh* sanctioned plaintiff's "reli[ance] on the FDA regulation merely to establish the standard or duty which defendants allegedly failed to meet," distinguishing it from a prohibited private cause of action under the FDCA. *Id.*; *see also Cottrell, Ltd.*, 191 F.3d at 1252 (refusing "to limit the scope of the Lanham Act absent circumstances that inherently require interpretation of FIFRA regulations and/or EPA approvals").

This is necessary because, although the court of appeals expressly noted the possibility that the FDA could take action if it believed a label to be misleading (*Pom Wonderful*, 679 F.3d at 1178), it is unlikely to do so. As Respondent concedes, "FDA lacks the resources to pursue individual actions against each manufacturer that adopts a deceptive label." Brief in Opposition to Petition for Writ of *Certiorari* at 16, *Pom Wonderful, LLC v. The Coca Cola Co.*, No. 12-761 (Feb. 22, 2013); *See* Petition for a Writ of *Certiorari* at 25-27, *Pom Wonderful, LLC v. The Coca Cola Co.*, No. 12-761 (Dec. 2012); *see also Cannon v. Univ. of Chicago*, 441 U.S. 677, 706–08 nn.41–42 (1979) (private right of action under Title IX of the Education Amendments of 1972 would not frustrate the legislative scheme's underlying purpose; Department of Health, Education, and Welfare itself recognized it did not have the resources to redress individual injuries).

Thus, a private Lanham Act challenge will likely be the sole action taken in response to a significant amount of deceptive conduct by food manufacturers, despite the fact that such conduct also violates FDA statutes or regulations. The ability of Lanham Act claimants to base their claims in part on non-compliance with FDA requirements would only serve to give effect to the FDCA and NLEA and other regulations.

CONCLUSION

For the reasons set forth herein, AIPLA respectfully requests the Court to vacate and remand the decision of the court of appeals for further proceedings.

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AMICUS CURIAE BRIEF

RECORD AND BRIEFS

APR - 2 2014

No. 12-761

IN THE

Supreme Court of the United States

POM WONDERFUL LLC,

Petitioner,

v.

THE COCA-COLA COMPANY,

Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AND THE GROCERY MANUFACTURERS ASSOCIATION AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

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INTEREST OF AMICI CURIAE[1]

The Chamber of Commerce of the United States of America ("Chamber") is the world's largest business federation. It represents 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the nation. The Chamber advocates its members' interests before Congress, the executive branch, and the courts, and it regularly files amicus curiae briefs in cases raising issues of vital concern to the business community.

The Grocery Manufacturers Association ("GMA") is a trade association of food and beverage companies. Founded in 1908, GMA is an active, vocal advocate for its member companies and a trusted source of information about the industry and products consumers rely on every day. The association and its member companies are committed to meeting the needs of consumers through product innovation, responsible business practices, and effective public policy solutions.

The Chamber's and GMA's member companies do business in highly regulated sectors, including the food industry. For their business practices to be efficient, predictability and uniformity are key; fragmented

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1. No counsel for a party authored this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person, other than amici curiae, their members, or their counsel, made a monetary contribution that was intended to fund preparing or submitting this brief. The parties have consented to the filing of this brief.

regulatory authority invites duplicative, burdensome regimes that increase production costs and the prices consumers must pay. Thus, both the Chamber and GMA have an acute interest in preserving unitary regulatory frameworks, particularly those—like the Food, Drug, and Cosmetic Act—that provide a balanced, nationwide business environment.

SUMMARY OF THE ARGUMENT

Permitting Pom to go forward with its Lanham Act challenge to Coca-Cola's labeling of its Pomegranate Blueberry Flavored Blend of Five Juices would defeat Congress's goals in delegating comprehensive, nationwide food-labeling authority to the Food and Drug Administration ("FDA") under the Federal Food Drug and Cosmetic Act of 1938 ("FDCA"). Since 1938, FDA has exercised broad prescriptive food-labeling authority for the benefit of consumers. Concomitantly, Congress has ensured that food manufacturers can rely on compliance with FDA regulations to market their products free from challenge under state law or other private actions that seek to enforce, directly or indirectly, the misbranding standards of the FDCA by imposing judicial interpretations that differ from FDA's regulatory positions.

But defeating Congress's assurance of national uniformity is Pom's precise aim. Pom would have Lanham Act juries throughout the country reach differing judgments about whether Coca-Cola's label is misleading and would in turn impose conflicting remedies. Coca-Cola might need to call its product "Apple Grape Blend of Five Juices" in Arkansas, "Apple, Grape, Pomegranate,

Blueberry, Raspberry Juice" in Maine, and "Five Juice Blend" in Washington. And it might need to convey that name in one font size in California, another font size in Minnesota, and yet another font size in New York. Avoiding such variation is why Congress granted FDA unified food-labeling authority, banned private rights of action to enforce the FDCA, and expressly preempted states from enforcing any food-labeling requirement not "identical" to the FDCA and FDA regulations. This is a comprehensive federal food-labeling regime.

Pom's Lanham Act claim is thus precluded, and cannot be resurrected under *Wyeth v. Levine*, 555 U.S. 555 (2009). *Levine* addressed a state-law verdict arising from Wyeth's failure to satisfy its FDCA duty to accommodate new post-approval safety information by modifying its label warnings; it was a *parallel* state-law proceeding. Pom's challenge is more properly analogized to *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466 (2013), which sustained preemption under the FDCA of a claim against an FDA-compliant manufacturer despite the availability of means by which the manufacturer could have prevented the injury to the plaintiff. "[I]f federal law gives an individual the right to engage in certain behavior that state law prohibits, the laws would give contradictory commands notwithstanding the fact that an individual could comply with both by electing to refrain from the covered behavior." *Levine*, 555 U.S. at 590 (Thomas, J., concurring in the judgment). Prohibitions arising from the general legal standard of the Lanham Act clearly fall within the same analysis.

The government's middle-ground position—in which FDA's "affirmative" regulations are preclusive but its

decision to afford labeling flexibility in other areas is not—is equally indefensible. FDA's conscious decision not to constrain certain aspects of the product's labeling reflects its considered judgment just as much as the agency's decision to afford manufacturers some latitude in choosing, for example, the product's name. Like Pom, moreover, the government would give business competitors greater rights under the Lanham Act than consumers hold under state law given the FDCA's express preemption of non-identical state-law claims. Indeed, FDA regulations acknowledge that the very kinds of labeling claims that would not be precluded under the government's theory would still be expressly preempted because they impose requirements different from those promulgated by the agency. Nothing in the FDCA's history suggests that Congress intended to wipe out non-identical state claims expressly only to see national uniformity demolished through the Lanham Act.

At most, then, Lanham Act claims challenging food labeling should be sustained only if they parallel FDA regulations. But Pom cannot prevail even under this forgiving method of reconciling the two laws. Pom's claim with regard to the juice product's name affirmatively contradicts FDA's regulation allowing the use of the name Coca-Cola chose. And Pom's claim regarding the "prominence" of certain words on the label, as well as its challenge to the size of certain graphics on the label's "vignette," likewise seek to impose requirements different from and in addition to FDA regulations. Accordingly, the decision below should be affirmed.

ARGUMENT

I. The FDCA Comprehensively Regulates Food Labeling To Educate Consumers And Ensure National Uniformity.

Seeking to justify an interpretation of federal law that would grant it an unrestricted right to bring Lanham Act claims against food labeling, Pom argues that the Lanham Act claims it presses are fully compatible with the FDCA because "the FDCA's misbranding provisions seek principally to protect public health and safety," while the "Lanham Act is intended to protect against unfair competition." Pet. Br. 6-7. But that self-serving description of the FDCA's purpose and scope is patently underinclusive. It grossly mischaracterizes FDA's longstanding consumer-protection mandate under the FDCA.

As early as 1906, Congress made clear that food labeling presents unique problems calling for a national legislative response. The Pure Food and Drug Act of 1906 ("1906 Act") prohibited the manufacture and interstate shipment of "any article of food or drugs which is adulterated or misbranded." Pub. L. No. 59-384, 34 Stat. 768, §§ 1-2 (1906). The law was a consumer-protection measure aiming "to enable purchasers to buy food for what it really is." *United States v. Ninety-Five Barrels (More or Less) Alleged Apple Cider Vinegar*, 265 U.S. 438, 443 (1924). But the 1906 Act defined "misbranding" in general terms suited to *ex post* review. A food would be misbranded, for example, if it were "labeled or branded so as to deceive or mislead the purchaser" or if its label bore a false or misleading "statement, design, or device

regarding ... the ingredients or substances contained therein." 34 Stat. 770, § 8. The sole affirmative labeling condition required that packages that state their contents "in terms of weight or measure" do so "plainly and correctly." *Id.*

"One of the principal objects of a national pure-food law is to obtain uniformity of food standards among the States." H.R. Rep. No. 59-2118, pt. 1 at 4 (1906). But the 1906 Act's potential was capped by its prohibitory terms and its ill-defined grant of power to implementing agencies. The law empowered the Secretary of Agriculture, among others, to make "uniform rules and regulations," 34 Stat. 768, § 3, but it was mostly "negative in character," *Hearings on H.R. 6906, H.R. 8805, H.R. 8941, and S. 5 before the House Subcomm. of the Comm. on Interstate and Foreign Commerce*, 74th Cong., 1st Session, at 44 (1935) (Statement of W.G. Campbell). Instead of prescribing what information food labels must convey, it spoke mainly to what manufacturers could *not* say. In the words of Walter G. Campbell, FDA chief in the 1930s, these early provisions "say you must not make a statement that is false or misleading, but they do not require you to make affirmatively a statement that is informing." *Id.* Thus, the Bureau of Chemistry, FDA's predecessor agency, could police misbranding violations, 34 Stat. 769, § 4, but lacked authority to implement its own prescriptive labeling regulations, F.D. No. 1, Reg. 14; FDA, *The Story of the Laws Behind the Labels*, Part II (1981) ("[The 1906 Act] enabled the Government to go to court against illegal products but lacked affirmative requirements to guide compliance.").[2]

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2. http://www.fda.gov/AboutFDA/WhatWeDo/History/Overviews/ucm056044.htm.

By the 1930s, the 1906 Act was viewed as insufficiently "broad in its scope to meet the requirements of consumer protection under modern conditions." H.R. Rep. No. 75-2139, pt. 1, at 1 (1938). To overcome these shortcomings, the Food Drug and Cosmetic Act of 1938 took a different approach. Like its predecessor, the FDCA was "primarily ... a consumers' measure," S. Rep. No. 74-361, pt. 1, at 3 (1935), designed to "safeguard[] the public health" and "prevent[] deceit upon the purchasing public," H.R. Rep. No. 75-2139, pt. 1, at 1 (1938). But the FDCA "strengthen[ed] and extend[ed]" federal power in important ways. S. Rep. No. 74-361, pt. 1, at 1 (1935). Requiring "[i]nformative labeling of foods as to quality and composition ... for the information and guidance of consumers" was a much-needed "improvement[] over existing law." H.R. Rep. No. 75-2139, pt. 1, at 2 (1938). The FDCA added a series of affirmative labeling requirements manufacturers now needed to honor to avoid misbranding. Pub. L. No. 75-717, 52 Stat. 1047, § 403 (codified as amended at 21 U.S.C. § 343); Statement of W.G. Campbell at 45 (S.B. 5 "offer[s] requirements for affirmative labeling which will make possible the purchase more intelligently and therefore more discriminatingly of food and drug products").

Congress further granted unprecedented power to FDA to "promote honesty and fair dealing in the interest of consumers." 52 Stat. 1046, § 401 (codified as amended at 21 U.S.C. § 341); *see also* 21 U.S.C. § 393(b)(2). In a calculated departure from the 1906 Act, Congress gave FDA prescriptive power to require labeling of foods. This delegation enhanced the 1906 Act, under which "[t]he government [lacked] authority and procedures for setting standards that would have the force of law." Oscar E. Anderson Jr., *Pioneer Statute: The Pure Food and Drugs*

Act of 1906, 13 J. Pub. L. 189, 195 (1964). Federal standards were "absolutely essential" to FDA's consumer-protection mission. Statement of W.G. Campbell at 45.

After 1938, FDA could condition food marketing on compliance with positive rules designed to enable consumers to make informed choices and compare commonly named items. 83 Cong. Rec. 7,774 (1938) (Statement of Rep. Lea) (FDA "is clothed with very broad authority for the purpose of enforcement, to make regulations to carry out the law that is proposed."). And to fortify FDA's new role, the FDCA assigned enforcement power exclusively to FDA. "All ... proceedings for the enforcement, or to restrain violations of, th[e] Act" could be brought only "in the name of the United States." 52 Stat. 1046, § 307 (codified as amended at 21 U.S.C. § 337). Thus, FDA could harmonize interpretation and application of the FDCA and its regulations, avoiding the risk that private, regulation-based lawsuits would impose disjointed commands on food manufacturers.

National uniformity was as much an object in 1938 as it had been in 1906. Like the framers of the 1906 Act—who expressed concern that interstate commerce had been "largely nullified as to food products by the varying requirements as to standards and labels in different States"—lawmakers in the 1930s saw a need for "[g]reater uniformity" in food-industry oversight. H.R. Rep. No. 59-2118, pt. 1, at 4 (1906); S. Rep. No. 74-361, pt. 1, at 3 (1935) ("The States have unanimously urged the Federal Government to take leadership in modernizing existing law.").

In enacting the most recent food-labeling legislation—the Nutrition Labeling and Education Act of 1990 ("NLEA")—national uniformity was a central concern. Whereas the framers of the 1906 Act thought to "invite" the states "to adopt the same standard," 40 Cong. Rec. 8,961 (1906) (Statement of Rep. Richardson), the NLEA mandated it. While prescribing detailed nutrition-labeling requirements, the NLEA added an express preemption provision to the FDCA barring States from "directly or indirectly establish[ing] ... any requirement for the labeling of food of the type required by" a range of FDCA provisions unless it is "identical to" the federal counterpart. 21 U.S.C. § 343-1(a)(2).

FDA has responded by proactively regulating food labels to enhance consumer choice. Juice producers, in particular, must comply with a unique layer of rules on top of the baseline scheme governing foods generally. Like all food labels, the "principal display panel" of every juice container must bear "as one of its principal features a statement of the identity of the commodity." 21 C.F.R. § 101.3(a). For "[b]everages that contain fruit or vegetable juice," the FDA prescribes the "common or usual name" with great specificity. *Id.* § 102.33; 21 U.S.C. § 343(i). If a beverage is a "blend of single-strength juices" and the display label names more than one juice, "the names of those juices ... must be in descending order of predominance by volume." 21 C.F.R. § 102.33(b). If a blend contains juices that are not named on the display label, "the common or usual name for the product shall indicate that the represented juice is not the only juice present (e.g., 'Apple blend; apple juice in a blend of two other fruit juices.')." *Id.* § 102.33(c).

Notably, FDA has concluded that a juice blend's common or usual name may reflect a juice that "is not the predominant juice" if the name either "[i]ndicate[s] that the named juice is present as a flavor or flavoring (e.g., 'Raspcranberry'; raspberry and cranberry flavored juice drink)" or "[i]nclude[s] the amount of the named juice, declared in a 5-percent range ...." *Id.* § 102.33(d). Coca-Cola chose the former. *Infra* 30.

Other information also is required. Along with the statement of identity, for example, the principal display panel must reflect a net quantity declaration. 21 U.S.C. § 343(e). Any beverage that "purports to ... contain[] vegetable or fruit juice" must also bear a declaration of the total percentage of juice. *Id.* § 343(i)(2); 21 C.F.R. § 101.30(e). Juice containers, like other foods, must further identify component ingredients, listed in descending order of predominance by weight. 21 C.F.R. § 101.4(a)(1). And the information panel must bear a "Nutrition Facts" label, which, in turn, can disclose "[o]nly those nutrients listed in FDA's nutrition regulations, as mandatory or voluntary components of the nutrition label." FDA, *A Food Labeling Guide: Guidance for Industry*, at 25, 27 (rev. Jan. 2013).

Presentation is as much controlled as content. Under the FDCA, a food is misbranded

> [i]f any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and

> understood by the ordinary individual under customary conditions of purchase and use.

21 U.S.C. § 343(f). FDA has defined ways in which "[a] word, statement, or other information required by or under authority of the act" may lack "prominence and conspicuousness." 21 C.F.R. § 101.15(a).

For many labeling components, FDA also overlays its general prominence regulations with specific rules. A food's statement of identity must, *inter alia*, "be presented in bold type on the principal display panel, [and must] be in a size reasonably related to the most prominent printed matter on such panel ...." *Id.* § 101.3(d). On the information panel, a juice's percentage-juice declaration must be placed "[n]ear the top ... with no other printed label information appearing above the statement except the brand name, product name, logo, or universal product code." *Id.* § 101.30(e) (detailing declaration size and typeface). For the neighboring Nutrition Fact label, FDA regulations specify the content, relative type-sizes, and arrangement of the required data. *Id.* § 101.9. "In the interest of uniformity of presentation" FDA even urges manufacturers to comply with other, permissive specifications. *Id.* § 101.9(d).

Collectively, the 1906 Act, the FDCA, and the NLEA amendments constitute nearly a century of congressional effort to empower consumer choice through labeling regulation. The comprehensive end-result vindicates two related interests: protecting consumers from deceptive trade practices and "provid[ing] national uniformity where it is most necessary ... ." 136 Cong. Rec. 33,427 (1990) (Statement of Sen. Mitchell); 58 Fed. Reg. 2462,

2462 (Jan. 6, 1993). Congress has long understood that "consistent, enforceable rules," H.R. Rep. No. 101-538, at 3338 (1990), ensure that "the food industry can market its products efficiently in all 50 States in a cost-effective manner," 58 Fed. Reg. at 2462. "A national food processor understandably finds it difficult to comply with numerous conflicting and inconsistent State and local laws." 136 Cong. Rec. 20,418 (1990) (Statement of Rep. Waxman). Thus, federal labeling legislation has aimed to "provid[e] complete and meaningful information to consumers without being overly burdensome on industry." 136 Cong. Rec. 35,095 (1990) (Statement of Rep. Madigan); *id.* ("[T]he bill provides industry with uniformity of law in a number of important areas ... that will permit them to conduct their business in an efficient and cost-effective manner."); 136 Cong. Rec. 20,418 (1990) (Statement of Rep. Waxman) (this point "has particular appeal with respect to food labels").

National uniformity also reflects Congress's desire to convey "certain items of information deemed essential to the consumer." Frederick H. Degnan, *The Food Label and the Right-to-Know*, 52 Food & Drug L.J. 49, 51 (1997). "[L]imits are necessary so that the emphasis is on the required information, and that the additional information does not clutter the food label or mislead or confuse the consumer." 58 Fed. Reg. at 2081.

In sum, the FDCA "has been carefully crafted to limit the amount of information that can be required to appear on the food label." Degnan, *supra*, at 50. Rather than police malpractices, FDA has exercised its power to determine what reasonable consumers should know when making purchases. Juice manufacturers, in turn,

can market their products only if their labels comply. Against this backdrop, "[i]t does not help the [FDA] ... to have myriad state labeling laws with each trying to 'go one better' than the FDA." 2 James T. O'Reilly, Food and Drug Administration § 25.30. Nor are the FDCA's goals advanced by independent, and potentially conflicting, Lanham Act determinations whether food labels are misleading.

II. Food-Labeling Requirements That Are Not "Identical" To Those Imposed Under The FDCA Are Precluded.

A. Pom's Assertion That The FDCA Merely Establishes A "Floor" Is Contrary To The Statute And This Court's Decisions.

The parties agree that the FDCA and Lanham Act must be reconciled, Pet. Br. 19-20; Resp. Br. 18; *see also* U.S. Br. 11, 18; and there can be no question that the FDCA controls where the two overlap, as a specific law takes precedence over a general one, Resp. Br. 18-21; U.S. Br. 17-18; *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384 (1992); *Nw., Inc. v. Ginsberg*, 572 U.S. __ (2014) (Slip Op. at 8). That interpretive canon has special force when, as here, "Congress has enacted a comprehensive scheme and has deliberately targeted specific problems with specific solutions." *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 132 S. Ct. 2065, 2071 (2012) (citation and quotations omitted).

Pom seeks to evade reconciliation by incorrectly labeling the FDCA regulation "a floor—but not a ceiling—on the adequacy of labeling." Pet. Br. 32. The 85-year course of federal food-labeling law reflects Congress's

abiding intent to aid consumers and manufacturers alike by framing a comprehensive unitary regime. Congress first barred misbranding generally, then imposed affirmative labeling requirements, vested FDA with supervening regulatory power, and secured to the federal government exclusive enforcement authority. Later still, it gave the FDCA's core food-labeling requirements express preemptive force. Consistently, Congress has sought to "obtain uniformity of food standards among the States." H.R. Rep. No. 59-2118, pt. 1, at 4 (1906). In light of this history, Pom's claim that Congress merely created a minimum standard to be supplemented by private actions is unsustainable.

According to Pom, *Levine* nevertheless confirms its interpretation of the FDCA because the Court "held that despite FDA's specific approval of the precise label being challenged, the plaintiff's tort claim was not preempted." Pet. Br. 32. But *Levine* arose from circumstances quite different from the present case. Resp. Br. 29-30; U.S. Br. 20-21. The question in *Levine* was whether the FDCA's new drug-approval process impliedly preempted State law. 555 U.S. at 565-66. Here, however, the Court must reconcile two *federal* statutes in a way that ensures consistency with the FDCA's centralization of federal authority in the FDA and broad *express* preemption clause. Both distinctions are crucial. Implied preemption of Levine's state failure-to-warn claim threatened to trench on the historic powers of the states in a way this dispute does not. *Levine*, 555 U.S. at 587-88 (Thomas, J., concurring in the judgment). And Congress's failure to include an express preemption clause was considered "powerful evidence" that it "did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness," *id.* at 575, an inference that cannot be drawn here, U.S. Br. 20.

The new drug-approval regime reviewed in *Levine* and the food-labeling regime at issue here function very differently. "[I]t has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times." *Levine*, 555 U.S. at 570-71. The new drug-approval labeling regime is a bottom-up process in which the manufacturer "is charged both with crafting an adequate label and with *ensuring that its warnings remain adequate as long as the drug is on the market.*" *Id.* at 571 (emphasis added). Accordingly, the *Levine* Court was addressing an FDA labeling regime where drug manufacturers were required to modify their labels as experience accumulated.

By contrast, FDA's food-labeling regime prescribes essential elements of food labeling to which manufacturers must conform without deviation. The elements of Coca-Cola's labeling that Pom attacks were not crafted by Coca-Cola and then submitted for approval to an overburdened federal agency. FDA's top-down prescriptive regulations specify almost every detail of the label's content and appearance. The continuing duty that led the Court to conclude there was no direct conflict between the FDCA's new drug-approval regime and Levine's state-law claim is absent here.

Moreover, *Levine* undermines Pom's position that the FDCA is a "floor" *even in the drug-labeling setting. Levine* did not question the pre-emptive effect of FDA's labeling approval when originally issued. But as the holder of an approved New Drug Application (NDA), Wyeth was required under the FDCA to monitor the safety of its product in use and to take corrective action if experience disclosed a serious risk of unexpected injury. *Id.* at 570-

51. FDA regulations consequently "permitted Wyeth to unilaterally strengthen its warning" without prior FDA approval if new evidence warranted such action. *Id.* at 573. *Levine* held that states could supplement FDA enforcement of an NDA holder's continuing monitoring responsibility by permitting injured plaintiffs to recover when approved drug labeling had not been properly updated.

The Court's decision in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), confirms that the FDCA is not a floor. There, the plaintiffs brought state-law claims analogous to those successfully pursued in *Levine*; the plaintiffs' injuries, however, were caused by a generic drug—marketed pursuant to an ANDA approval. *Id.* at 2574-75. That distinction proved decisive, for while "[a] brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label," a generic manufacturer only "is responsible for ensuring that its warning label is the same as the brand name's." *Id.* at 2574. Unlike brand name labels, the FDCA required "changes to generic drug labels only ... to match an updated brand-name label or to follow the FDA's instructions." *Id.* at 2575. Had the generic manufacturers "independently changed their labels to satisfy their state-law duty, they would have violated federal law." *Id.* at 2578. Mensing's state-law claims thus were preempted.

If, as Pom contends, FDCA labeling requirements were a "floor," *Mensing* would have presented immense difficulty. States would be free to impose damages awards on generic manufacturers who were acting in compliance with federal law and subject to FDA enforcement for unilaterally modifying their labels. The Court resolved

this difficulty by holding that compliance with the FDCA by generic manufacturers preempted state-law claims based on failure to label above the alleged federal floor. *Id.* at 2581 n.8.

Pom responds that this case is not like *Mensing* because "nothing in the FDCA or FDA's regulations prevented Coca-Cola from making its label ... compliant with the Lanham Act." Pet. Br. 24; Pet. Br. 22 (claiming that "Coca-Cola was not required" under the FDCA "to use the misleading name it selected for its product"). But that argument is foreclosed by this Court's decision in *Bartlett*. There, the plaintiffs attempted to circumvent *Mensing* by arguing that the generic drug manufacturer could respond to inadequate labeling consistently with the FDCA and New Hampshire law by ceasing to sell its product. *Bartlett*, 133 S. Ct. at 2477. The Court held that preemption could not be so easily defeated. The FDCA granted the manufacturer the federal right to distribute its generic drug in interstate commerce so long as it complied with the FDCA, FDA's regulations, and any parallel state-law duties. *Id.* at 2471; 21 U.S.C. § 355(a). States could not condition that right on compliance with additional state-imposed labeling requirements. 133 S. Ct. at 2478 n.5. Similarly, Coca-Cola's right to distribute its juice in compliance with the FDCA and FDA regulations cannot be conditioned on added labeling requirements imposed by state law or the Lanham Act.

Bartlett thus defeats Pom's claim that Coca-Cola's ability to comply with the FDCA and different duties under state law or the Lanham Act avoids preemption and preclusion. Invoking its unchallenged Article I authority to regulate the interstate sale of food, Congress

determined that Coca-Cola was entitled to distribute its juice product so long as its label complied with FDA regulations. There is no support for Pom's contention that Congress further conditioned that right on Lanham Act compliance. Strict compliance with FDA's many labeling requirements "would be 'all but meaningless'" if it did not provide insulation from liability for lack of compliance with conflicting legal regimes. *Id.* at 2477 (quoting *Mensing*, 131 S. Ct. at 2579).

Justice Thomas's *Levine* concurrence anticipated this point; he recognized there was no "'direct conflict'" between the FDCA and the state-law duty to strengthen the label's warning because "FDA regulations require a drug manufacturer—after initial federal approval of a drug's label—to revise the federally approved label 'to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug.'" 555 U.S. at 592 (quoting 21 C.F.R. § 201.80(e)). Accordingly, "nothing in the text of the statutory or regulatory scheme necessarily insulat[ed] Wyeth from liability under state law simply because the FDA has approved a particular label." *Id* at 593.

But Justice Thomas distinguished the situation confronting Wyeth from one in which state law imposed duties beyond what is required to secure and maintain federal approval. As he explained, and *Bartlett* eventually confirmed, "if federal law gives an individual the right to engage in certain behavior that state law prohibits, the laws would give contradictory commands notwithstanding the fact that an individual could comply with both by electing to refrain from the covered behavior." *Id.* at 590; Caleb Nelson, *Preemption*, 86 Va. L. Rev. 225, 261 (2000)

("Imagine, for instance, that a valid rule of federal law gives workers the right to join a labor union (subject to certain qualifications), while state law purports to prohibit all union membership. It is physically possible for workers to comply with both laws by refraining from joining a union. But ... the state law is preempted: A court that enforced the state-law prohibition would be ignoring the federal-law right."); *Gordon v. New York Stock Exchange, Inc.*, 422 U.S. 659, 689-90 (1975).

That is the situation here. Manufacturers of blended juices are not charged under the FDCA or FDA regulations with a continuing duty to "analyze[] ... accumulating data and add[] a stronger warning" concerning the product's safety if the new information warrants that step. *Levine*, 555 U.S. at 570. Thus, Pom does not seek to use the Lanham Act to enforce a standard paralleling the FDCA's labeling regime. Pom instead seeks to constrain Coca-Cola's federal right to sell blended juice in interstate commerce under the approved federal label by imposing a more restrictive rule under the Lanham Act. The fact that Coca-Cola could comply with both does not negate the direct conflict.

B. The Government's Acknowledgement of Preclusion Under The FDCA Is Unduly Constrained.

The government correctly rejects Pom's "floor" argument with regard to FDA's juice-labeling regulation. U.S. Br. 16-21. FDA's regulation authorized the product name Coca-Cola chose, *infra* 29-31, and "'[t]he conflict' between the changes petitioner seeks to impose under the Lanham Act and FDA's juice-naming regulation 'does

not evaporate' because the 'regulation simply permits, but does not compel,' the name respondent chose," U.S. Br. 18 (alteration in original) (quoting *Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 155 (1982)). Allowing Pom's challenge to "the naming aspect of petitioner's claim to proceed ... would not supplement FDA's enforcement resources; it would supplant FDA's regulatory judgment." U.S. Br. 19 (citation omitted).

The government's conclusion with respect to naming follows directly from the legal principles set forth above: even though Coca-Cola could have refrained from using pomegranate or blueberry in its product name "without running afoul of [FDA's] regulations," U.S. Br. 18, a "successful challenge to a name that complies with FDA's juice-naming regulation" would *still* conflict with a right afforded to the manufacturer under the FDCA, U.S. Br. 20. Accordingly, the government correctly concludes that "the Lanham Act must give way." U.S. Br. 20.

But the government attempts to limit this interpretation to when "the FDCA or its implementing regulations affirmatively authorizes [a] labeling decision or embodies a determination by FDA that it is not misleading." U.S. Br. 23. That position is too narrow for several reasons.[3]

First, the complete overlap of the Lanham Act's general prohibition of commercial practices that "misrepresent[] the nature, characteristics, [or] qualities ... of [a seller's]

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3. The government's interpretation of the FDCA's preclusive force, unlike its interpretation of FDA's labeling regulations, is not entitled to judicial deference. *Mensing*, 131 S. Ct. at 2575 n.3 (citing *Levine*, 555 U.S. at 576).

or another person's goods," 15 U.S.C. § 1125(a)(1)(B), and the FDCA's specific prohibition on marketing goods whose "labeling is false or misleading," 21 U.S.C. § 343(a)(1), must be reconciled to respect Congress's decision to restrict FDCA enforcement to FDA, acting "in the name of the United States." *Id.* § 337(a). Any contention that FDA's labeling regulation was or is inadequate must be addressed to the agency rather than through an *ad hoc* judicial process under the Lanham Act. Pet. App. 12a.[4] Tellingly, Congress allowed non-FDA enforcement actions under the FDCA—*but only by States*. 21 U.S.C. § 337(b)(1) ("A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 341, 343(b), 343(c), 343(d), 343(e), 343(f), 343(g), 343(h), 343(i), 343(k), 343(q), or 343(r) of this title if the food that is the subject of the proceedings is located in the State.").

Second, FDA's decision *not* to regulate is as significant as its affirmative commands. FDA's regulatory mandate goes beyond dealing with discrete labeling elements; the agency is charged with ensuring that the label in its entirety enables informed consumer choice. *Id.* §§ 341, 393(b). By establishing which labeling elements should be mandatory and which should be subject to manufacturer discretion, FDA necessarily determines that conforming labels accord with its statutory mission. That FDA allows food manufacturers to exercise some marketing discretion does not undermine its consumer-protection

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4. This does not mean that the Lanham Act is inapplicable to food manufacturers. Resp. Br. 52-53. It would still apply, for example, to matters not addressed by the FDCA, such as trademark violations and fraudulent product endorsements.

regime. The FDCA "ensure[s] that the label communicates essential information to consumers" consistent with FDA's expert judgment, while also giving businesses flexibility to differentiate their product and compete in the marketplace. 58 Fed. Reg. at 2920.

Third, and decisively, the government incongruously advocates far greater rights under the Lanham Act for competitors than consumers invoking state law. The NLEA provides that "no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce ... any requirement for the labeling of food of the type required by" Sections 343(f) and (i), among other provisions, "that is not *identical* to the requirement of such section ...." 21 U.S.C. § 343-1(a)(3) (emphasis added). The ordinary meaning of "identical" is "[t]he same; not different or other," or "exactly alike or equal." Webster's New Int'l Dictionary 1236 (2d ed. 1936). FDA has thus concluded that, within its compass, Section 343-1(a)'s "preemptive effect is quite broad." 58 Fed. Reg. at 2471. It makes no difference whether a state requirement affirmatively conflicts with the FDCA or FDA regulation. Section 343-1(a) preempts any state requirement, regardless of its "specific words," that "directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food" that are not "imposed by or contained in" the relevant FDCA provision or FDA regulation. 21 C.F.R. § 100.1(c)(4).

For state labeling requirements "of the type" imposed under Sections 343(f) and (i), then, "consistency is not the test; identity is." *Turek v. Gen. Mills, Inc.*, 662 F.3d

423, 426-27 (7th Cir. 2011). States are not free to add labeling requirements merely "consistent with [those] imposed by the [FDCA]." *Id.* at 427. "State laws that impose affirmatively different labeling requirements from federal law in these areas will be preempted." *Koenig v. Boulder Brands, Inc.*, --- F. Supp. 2d ----, 2014 WL 349706, at *5 (S.D.N.Y. Jan. 31, 2014). Put simply, state labeling requirements must parallel federal labeling requirements. *In re PepsiCo, Inc., Bottled Water Mktg. and Sales Practice Litig.*, 588 F. Supp. 2d 527, 538-39 (S.D.N.Y. 2008) (explaining that to "permit[] state requirements [to] go beyond federal law as long as federal law does not expressly prohibit or permit the specific labeling at issue" would contravene the "plain meaning" of Section 343-1).

The Seventh Circuit's *Turek* decision illustrates the point. There, a consumer brought state deceptive-trade-practices claims alleging that a "chewy bar" food label should have contained disclaimers about the bar's fiber content beyond what FDA had required. *Turek*, 662 F.3d at 425-26. Nutrient-content labeling is governed by Section 343(r)(1), which has preemptive force under the NLEA. 21 U.S.C. § 343-1(a)(5). Because "[t]he information required by federal law [did] not include" the disclaimers sought by the consumer, the state-law requirements were "not identical to the labeling requirements imposed ... by federal law" and gave way. *Turek*,662 F.3d at 427. Whether the added information would be "a good thing" or "consistent" with the FDCA was "irrelevant." *Id.* What mattered was the lack of identity.

This Court's interpretation of the preemptive force of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") is also instructive. Express preemption under

Section 343-1 of the FDCA is equal to (if not broader than) preemption under the FIFRA, which prohibits states from "impos[ing] or continu[ing] in effect any requirements for labeling or packaging *in addition to or different from* those required under [the FIFRA]." 7 U.S.C. § 136v(b) (emphasis added); *Turek v. Gen. Mills, Inc.*, 754 F. Supp. 2d 956, 959 (N.D. Ill. 2010) ("[S]everal courts have used the *Bates* test to determine the preemptive effect of [the FDCA]."), *aff'd as modified* 662 F.3d 423; *In re PepsiCo.*, 588 F. Supp. 2d at 533 (characterizing this Court's analysis of the FIFRA as "strikingly similar" to the proper framework for analyzing the FDCA); *cf. Mills v. Giant of Md., LLC*, 441 F. Supp. 2d 104, 108 (D.D.C. 2006) ("The scope of FDCA's preemption clause is much broader than FIFRA's.").

To survive express preemption under the FIFRA, a state requirement must be "equivalent to, and fully consistent with, the FIFRA's misbranding provisions." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 447 (2005). In other words, the state law must be strictly "parallel." *Id.*; *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) (applying similar reasoning to Medical Device Amendments of 1976). "[N]ominally equivalent labeling requirements" are not enough; the state laws must be "*genuinely* equivalent" to the federal rule, *Bates*, 544 U.S. at 454, or, in the words of the FDCA, "identical." "[A] manufacturer should not be held liable under a state labeling requirement subject to § 136v(b) unless the manufacturer is also liable for misbranding as defined by FIFRA." *Id.*

Accordingly, legislative or judicial state requirements imposing nutritional labeling rules "of the type" required by applicable FDCA provisions survive preemption under

Section 343-1(a) only if they are "identical to," "fully consistent with," and "genuinely equivalent" to the federal regime. Requirements to supplement an FDA-authorized use of "blend of juices" with percentage specifications or to make inflexible the prominence required of FDA-authorized terms like "Blend" are foreclosed to states.

Indeed, any other construction of Section 343-1(a) would render Section 343-1(b)(3) surplusage. *Duncan v. Walker* 533 U.S. 167, 174 (2001) ("It is our duty to give effect, if possible, to every clause and word of a statute."(internal quotations and citations omitted)). Under Section 343-1(b):

> Upon petition of a State or a political subdivision of a State, the Secretary may exempt from subsection (a) of this section, under such conditions as may be prescribed by regulation, any State or local requirement that—
>
> > (1) would not cause any food to be in violation of any applicable requirement under Federal law,
> >
> > (2) would not unduly burden interstate commerce, and
> >
> > (3) is designed to address a particular need for information which need is not met by the requirements of the sections referred to in subsection (a) of this section.

21 U.S.C. § 343-1(b).

If the labeling requirements given preemptive effect by Section 343-1(a) could be freely supplemented under state law, as Pom argues, Section 343-1(b) would be surplusage. And, if express preemption were limited only to those subjects affirmatively addressed by FDA, as the government claims, there would have been no need for subsection (3) since an informational need "not met by" the FDCA's labeling requirements already could be pursued under state law. Congressional authorization of state petitions to FDA reinforces Congress's determination to make the FDCA requirements exclusive absent an approved state-specific request.[5]

The government conveniently ignores the gap its interpretation creates between Lanham Act and state-law claims and the superior litigation rights it proposes to afford business competitors. U.S. Br. 25 & n.10. But there is no basis for permitting more extensive disruption of the FDCA labeling regime by competitor actions under the Lanham Act than consumer actions under state law. FDCA is designed to ensure "national uniformity" for covered labeling requirements. *See* Pet. Br. 31; U.S. Br. 25; U.S. Br. in Opp. to Cert. 11 (explaining that the NLEA "was designed to promote '[n]ational[ly] uniform nutrition labeling'"). The NLEA and Section 337(a) conclusively balance disclosure and uniformity interests, and this Court should honor that balance.

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5. It is no answer to say, as Pom does, that a state-law claim is insulated from preemption if framed in the general terms of Section 343(a). Pet. Br. 31. Congress's omission of this subsection from the FDCA's express preemption provision does not have the significance Pom ascribes to it. Section 343(a) enables parallel state actions but does not permit departing from identity limitations under Sections 343(f) and (i).

Congress's goal of national uniformity would be ill-served by the jigsaw arrangement that the government advocates. Lanham Act litigation risks presenting labeling questions properly entrusted to FDA to federal juries time and again, and each time for consideration *de novo*. There would not be just a single "Lanham Act" labeling standard to compete with FDA's regime. Quite the opposite. The policy judgments and expert decision-making Congress delegated to FDA would be decided and re-decided anew by different judges and juries in each Lanham Act labeling case across the nation.

Consider, for example, the FDCA's "common or usual name" provision, under which a food is misbranded if its label does not "bear[] ... the common or usual name of the food, if any there be ... ." 21 U.S.C. § 343(i). Although FDA is authorized to define "common or usual names" by regulation, not all foods have been so named. Nonetheless, because Section 343(i) is given preemptive force, FDA has correctly concluded that states may not establish their own "common or usual" names "for a food for which there is no specific Federal common or usual name." 58 Fed. Reg. at 2471. Even if a state's name were in full "conformance with" FDA naming principles, it would still be preempted. *Id.* "It would be a requirement of the type required by section [34]3(i)(1) of the act, but it would not be identical to the provisions that FDA has adopted under that section." *Id.*

Still, the government would incongruously allow that same preempted state-law claim to proceed under the Lanham Act, as FDA would not have "affirmatively authorize[d]" the manufacturer's choice of a name for a product that had not been given a prescribed common

name. This cannot be what Congress intended in opting for uniformity through a unified regulatory regime. It would indeed be "counterintuitive" to conclude that Congress sought to achieve national uniformity by cabining state experimentation with one hand while, with the other, endorsing an equally disruptive federal regime. U.S. Br. 25; *cf. Waymire v. Norfolk & W. Ry. Co.*, 218 F.3d 773, 777 (7th Cir. 2000) ("To allow a plaintiff to argue adequacy of warning claims under [the Federal Employers' Liability Act] but not under state law would undermine the railroad safety uniformity intended by Congress ....").

Nothing in this Court's precedent or the FDCA's history supports such a result. For whether the rule of decision is state or federal, "[a] multiplicity of tribunals and a diversity of procedures are quite as apt to produce incompatible or conflicting adjudications as are different rules of substantive law." *Garner v. Teamsters Local Union No. 776*, 346 U.S. 485, 490-91 (1953). In either case, it "is wholly inconsistent with the administrative power conferred upon the [FDA], and with the duty, which the [FDCA] casts upon that body, of seeing to it that the statutory requirement as to uniformity" and clarity of labeling is observed. *Tex. & Pac. Ry. Co. v. Abilene Cotton Oil Co.*, 204 U.S. 426, 440-41 (1907).

III. Pom's Lanham Act Claim Cannot Proceed When Coca-Cola's Label Complies With The FDCA And Its Implementing Regulations.

Even if, contrary to Section 337, Lanham Act plaintiffs were permitted to bring a claim that seeks to enforce a requirement parallel to the FDCA and FDA's implementing

regulations, Pom's action still would be foreclosed.[6] Far from paralleling FDA's regulations, Pom's Lanham Act claim regarding the content and presentation of Coca-Cola's labeling seeks to impose labeling requirements that are different from or in addition to those imposed by FDA. Pet. Br. 44 (Coca-Cola's liability under the Lanham Act "is independent of the application or interpretation of the FDCA or FDA's regulations.").

Pom principally attacks Coca-Cola's naming its product "Pomegranate Blueberry Flavored Blend of 5 Juices." Pet. App. 9a-10a; Pet. Br. 49-52. Pom claims that this name misleads consumers into perceiving the product as primarily containing pomegranate and blueberry juices when apple and grape juices are, in fact, the primary ingredients. Pet. Br. 10. In Pom's view, Coca-Cola could have—and thus should have—named its product after "the two primary juices in its product," apple and grape. App. 61a. But Coca-Cola's product name is specifically authorized by FDA regulations. Resp. Br. 38-42; U.S. Br. 13-16.

For a multiple-juice blend, such as this product, FDA regulations provide that non-predominant juices may

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6. Separately, Pom's claim may well be foreclosed by the Court's recent holding that a plaintiff bringing a Lanham Act false advertising claim "must plead (and ultimately prove) an injury to a commercial interest in sales or business reputation proximately caused by the defendant's misrepresentations." *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 572 U.S. ___ (2014) (Slip. Op. at 25); *see* Pet. App. 5a (noting the district court's holding "that Pom lacked statutory standing to pursue its state law claims" because "Pom had not established the statutory standing prerequisite of 'lost money or property'").

be named on the principal display panel so long as "the common or usual name for the product" meets one of two requirements:

> It must "[i]ndicate that the named juice is present as a flavor or flavoring (e.g., 'Raspcranberry'; raspberry and cranberry flavored juice drink)"; *or*
>
> It must "[i]nclude the amount of the named juice, declared in a 5-percent range."

21 C.F.R. § 102.33(d).

Coca-Cola follows the first of these alternatives. Resp. Br. 38-39; U.S. Br. 14. In FDA's considered judgment, complying with either command adequately "describe[s] the contribution of the named juice if it is not the predominant juice." 58 Fed. Reg. at 2921; *id.* ("FDA is providing in § 102.33(d)(1) that a multiple-juice beverage may use a product name that specifically shows that the named juice is used as a flavor.").[7] FDA has voiced confidence that "consistent use of" these terms will "help to reduce or remove consumer confusion." 56 Fed. Reg. 30,452-01, 30,461 (July 2, 1991). "Indicat[ing] that the named juice is present as a flavor or flavoring" ensures that the label "will not imply that the content of that juice is greater than is actually the case." 58 Fed. Reg. at 2921.

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7. Pom argues, for the first time, that "Pomegranate Blueberry Flavored Blend of 5 Juices" is somehow *not* a permissible common or usual name under Section 343(i) and 21 C.F.R. § 102.33(d)(1). Pet. Br. 49-52. This new theory finds no support in the existing record. Resp. Br. 40-41; U.S. Br. 21-23.

Pom disagrees. "By name alone," it maintains, "one would expect that the primary ingredients in Coca-Cola's ... Product are pomegranate and blueberry juice." App. 62a. To rectify this perceived shortcoming, Pom would have Coca-Cola name "the two primary juices in its product" on the principal display panel. App. 61a. But this is hardly "identical to" Section 343(i) and its implementing regulations. Pom's demand goes far beyond Section 343(i), and that alone should be enough to defeat the claim. Worse still, advocating a head-on collision with the policy judgments expressed in FDA regulations, U.S. Br. 16-21, Pom would invite precisely the kind of "conflicting and inconsistent" requirements that the FDCA is designed to foreclose.

Pom also challenges the prominence of the words "flavored Blend of Five Juices," which it claims enhances the misrepresentation caused by the product name. Pet. App. 10a-12a; Pet. Br. 10, 23-24. Within the common or usual name, Pom argues, the words "Pomegranate" and "Blueberry" wrongly "dwarf" the remainder of the product's name, "Flavored Blend of 5 Juices." Pet. Br. 2; Pet. App. 10a ("Pom focuses its labeling argument on how Coca-Cola presents the words 'Pomegranate Blueberry' and 'Flavored Blend of 5 Juices' on the product's label."). In other words, Pom seeks to introduce a type-size requirement into Coca-Cola's product name.

Again, however, Coca-Cola's choice of type size conforms to the FDCA's requirement that required label elements be sufficiently "prominent" to attract consumer attention. Under Section 343(f), a "statement ... required by or under authority of [the FDCA] to appear on the label" must be "prominently placed thereon with such

conspicuousness ... and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use." 21 U.S.C. § 343(f). While FDA "has not explicitly enunciated definitions of 'conspicuous' or 'prominent,'" it has fashioned a "strong standard" to give effect to Section 343(f). 58 Fed. Reg. at 2473. A food's statement of identity, for example, must "be presented in bold type on the principal display panel," must "be in a size reasonably related to the most prominent printed matter on such panel," and must "be in lines generally parallel to the base on which the package rests as it is designed to be displayed." 21 C.F.R. § 101.3(d). FDA also has set forth general factors that the agency may consider in evaluating whether a statement satisfies Section 343(f), *id.* § 101.15, and has adopted a specific regulation concerning the font size of the disputed labeling with which Coca-Cola fully complied, Resp. Br. 42-45.

Regardless, neither Section 343(f) nor any FDA regulation requires that a product's common or usual name be set in uniform type. Pet. Br. 47; U.S. Br. 28-29 & n.13. Pom therefore seeks to impose a prominence requirement under the Lanham Act as to the size of a common or usual name that is not "identical to" Section 343(f) or FDA regulations. At the very least, FDA has *not* specifically addressed "how [Coca-Cola should] present[] the words 'Pomegranate Blueberry' and 'Flavored Blend of 5 Juices' on the product's label." U.S. Br. in Opp. to Cert. 19 (citation and quotations omitted). By necessity, then, Pom's requirement is not identical to the existing FDCA regime. It was FDA's assessment that the specific requirement Pom seeks to impose here was not necessary to apprise consumers adequately of the product's contents. Permitting a court or jury to add type-size specificity

under the Lanham Act would impermissibly question FDA's regulatory judgment. Regardless, the type-size complaint cannot be separated from Pom's challenge to the product's name. Had Coca-Cola, as Pom demands, named its product "Apple Grape Blend of Five Juices," the type size of the words "Flavored Blend of Five Juices" would have no significance to Pom.

Finally, Pom belatedly takes issue with the "vignette" on Coca-Cola's label, which displays each of the five fruits represented in its product and, according to Pom, distorts the prominence of pomegranate and blueberry juices in the blend. Pet. Br. 52. Setting aside questions of waiver, Pet. App. 10a; Resp. Br. 45-46; U.S. Br. 30 n.14, Coca-Cola's vignette does not offend the FDCA regime. According to FDA, "it is not always necessary that the label of a multiple-juice beverage depict each juice in a vignette." 58 Fed. Reg. at 2921. Rather, "a vignette that pictures only some of the fruit ... in the beverage *would not be misleading* where the name of the food adequately and appropriately describes the contribution of the pictured juice." *Id.* (emphasis added). Because Coca-Cola's product name fully specifies that pomegranate and blueberry juices are flavorings, *supra* 30, Coca-Cola could have used a vignette displaying *only* pomegranates and blueberries. Thus, any live claim Pom might have with regard to the vignette is precluded because it seeks to impose a requirement different from the FDCA and FDA's regulations.

More broadly, Pom's arguments ignore or seek to override FDA's determination that the use of the word "flavored" properly communicates to consumers that pomegranate and blueberry juices blend into the product

to provide characterizing flavor. Pom likewise ignores Coca-Cola's FDA-mandated nutrition label disclosure of all five juices in its blend in order of importance. That listing enables interested consumers to ascertain that apple and grape juices are principal components, with pomegranate and blueberry juices—as the labeling communicates—being used for characterizing flavor and raspberry juice being of even less significance.

Thus, Pom cannot salvage its Lanham Act claim by claiming that it just echoes the general labeling mandate set forth in Sections 343(f) and (i) as opposed to FDA's interpretation of those provisions via regulation. The label conveys all information required by Sections 343(f) and (i). As for the name, Coca-Cola uses "the term 'flavor'" to "inform the consumer that the juice is present in an amount sufficient to flavor the beverage but [without] imply[ing] that the content of that juice is greater than is actually the case." 58 Fed. Reg. at 2921. As for the type size, "the ordinary individual who is interested in discovering and learning" the full product name can do so with "minimum examination of the package." 58 Fed. Reg. at 2473. And, as for the vignette, the FDA has already found that unrepresentative—even incomplete—vignettes are "not ... misleading where the name of the food adequately and appropriately describes the contribution of the pictured juice." 58 Fed. Reg. at 2921.

Pom's grievance thus is not that Coca-Cola has failed to comply with the FDCA or FDA's regulations. It is that FDA has not adequately prevented consumer misperception. Unlike in *Levine*, then, Pom does not seek to reinforce the federal standard through a parallel action. Rather, as in *Mensing* and *Bartlett*, Pom seeks to invoke

the Lanham Act to override FDA's judgment and defeat the labeling uniformity Congress mandated under the FDCA. That should be the end of the matter.

CONCLUSION

The Court should affirm the judgment of the court of appeals.

Respectfully submitted,

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April 2, 2014

AMICUS CURIAE BRIEF

Supreme Court, U.S.
FILED
APR 2 - 2014
OFFICE OF THE CLERK

No. 12-761

In the Supreme Court of the United States

POM WONDERFUL LLC,
Petitioner,

v.

THE COCA-COLA COMPANY,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

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QUESTION PRESENTED

Whether the court of appeals erred in holding that a private party cannot bring a Lanham Act claim challenging a product label regulated under the Food, Drug, and Cosmetic Act?

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INTEREST OF *AMICUS CURIAE*[1]

Amicus curiae DRI—the Voice of the Defense Bar, is a 22,500-member international association of defense lawyers who represent individuals, corporations, insurance carriers, and local governments involved in civil litigation. DRI has long been a voice for a fair and just system of civil litigation, seeking to ensure that it operates to effectively, expeditiously, and economically resolve disputes for litigants. To that end, DRI participates as amicus curiae in cases that raise issues of importance to its membership and to the judicial system. This is such a case.

DRI's interest here stems from its members' need to advise clients when to bring or defend against suits under the false advertising provision of the Lanham Act (15 U.S.C. § 1125(a)(1)(B)) and from their representation of clients whose products are subject to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq*. (FDCA). DRI believes it is critical for this Court to preserve Congress's uniform national regulatory scheme with respect to food labeling created by the FDCA and the Nutrition Labeling and Education Act of 1990, 21 U.S.C. § 343-1 (NLEA). The system does not permit private rights of action to enforce the FDCA or state law requirements for food labels that differ from the NLEA. DRI members' extensive litigation experience counsels that, when the category of

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[1] Pursuant to Rule 37.6, amicus certifies that no counsel for a party authored this brief in whole or in part and that no person or entity, other than amicus, its members, or its counsel, has made a monetary contribution to the preparation or submission of this brief. The parties have filed written consent to the filing of amicus briefs pursuant to Rule 37.

plaintiffs is expanded – here by potentially allowing private parties to bring claims under the Lanham Act, 15 U.S.C. § 1051 *et seq.*, for labels that are authorized by the FDCA – the job of advising or defending clients increases in difficulty; a difficulty that will be compounded by the lack of a uniform predictable standard. Unless this framework is preserved by precluding private parties from bringing Lanham Act claims, the practical, real world ramifications of private party suits that urge disparate and potentially mutually exclusive labeling requirements will undermine the regulatory approach Congress envisioned. The potential for multiple plaintiffs means that DRI members will be defending against myriad suits, each potentially insisting on a different label. This will result in conflicting standards impossible to know in advance. DRI's members and their food-and-beverage-manufacturer clients will be unable to create an acceptable label, thus thwarting any semblance of a regulatory safe harbor.

In addition to providing consumer information, labels have a branding aspect and manufacturers expend vast resources developing a label that is authorized under the law. If a label can be constantly attacked by competitors through litigation, it will undermine marketing efforts and become a costly drag on the market. Congress intended the regulatory scheme created by the FDCA and NLEA to allow manufacturers in the food industry to effectively and efficiently market their products nationwide. Senator Hatch emphasized amicus DRI's concern that any system that does not ensure uniformity burdens manufacturers by increasing the likelihood of litigation: "it is wrong to burden the manufacturer with

the fear of potentially 50 different lawsuits from 50 different State attorneys general, even if similar cases have been dismissed or settled." 136 Cong. Rec. S16607-02, 1990 WL 206648 (October 24, 1990). The situation would only be magnified if manufacturers were subjected to the whims of an infinite number of private parties enforcing their own notions of what constitutes an appropriate label. Amicus curiae DRI urges this Court to rule that the FDCA and NLEA establish a single nationwide standard that is enforced exclusively by the FDA. Accordingly, this Court should affirm the Ninth Circuit's decision here, which held that a private party cannot bring a Lanham Act claim challenging a product label that is authorized by the FDCA.

SUMMARY OF ARGUMENT

The decision of the court of appeals should be affirmed and this Court should hold that a private party cannot bring a claim under the general provisions of the Lanham Act to challenge a product label that is authorized under the specific requirements of the FDCA and NLEA, through which Congress intended to create a system of national uniformity in food labeling. When statutes seemingly conflict, as do the Lanham Act and FDCA here, courts must read them consistently whenever possible, *Kremer v. Chem. Const. Corp.*, 456 U.S. 461, 468 (1982), and give precedence to the more specific statute, *Busic v. U.S.*, 446 U.S. 398, 406 (1980).

Section 43(a) of the Lanham Act is designed to combat false advertising of any product or service, thereby protecting business entities against unfair competition. See 15 U.S.C. § 1127. To have standing in

a suit for false advertising under § 1125(a), "a plaintiff must allege an injury to a commercial interest in reputation or sales." *Lexmark Int'l, Inc. v. Static Control Components, Inc.*, 12-873, 2014 WL 1168967 (U.S. Mar. 25, 2014). Thus, competitors are likely to use the Lanham Act to avenge perceived wrongs. See *TrafficSchool.com, Inc. v. Edriver Inc.*, 653 F.3d 820, 827 (9th Cir. 2011). Like the Lanham Act, the FDCA also addresses false statements. But the FDCA, in conjunction with the NLEA, is directed toward consumer protection as well as to ensuring efficiency in operations and marketing for manufacturers. The FDCA and NLEA are more specific that the Lanham Act in determining whether a statement on a beverage label is false.

In enacting the FDCA and NLEA, Congress intended to protect consumers and provide guidance to manufacturers by establishing a national uniform system in food labeling. Congress sought to allow the food industry to "market its products efficiently in all 50 States in a cost-effective manner." State Petitions Requesting Exemption from Federal Preemption, 58 Fed. Reg. 2462-01 (Jan. 6, 1993). This included freedom from the potential of "50 different lawsuits from 50 different State attorneys general." 136 Cong. Rec. S16607-02, 1990 WL 206648 (October 24, 1990). Thus, allowing private parties to use the general provisions of the Lanham Act to bring a claim against a product label that complies with the specific requirements of the FDCA and NLEA would undermine the system of uniformity created by Congress.

The Ninth Circuit here and other courts have determined that in a comprehensively regulated area where the FDA has clearly spoken, it is not proper for a private party to bring a Lanham Act claim. The reasoning in the opinions is characterized as deference to Congress's decision to entrust food and drug labeling decisions to the FDA – which in essence recognizes Congress's intent to create a system of national uniformity in labeling. The decisions also respect the fact that, while the Lanham Act and the FDCA both share the common purpose of preventing false statements, the FDCA is directed more specifically to what is false or misleading on a food or beverage label. This Court should affirm the Ninth Circuit's decision here and hold that a private party cannot bring a Lanham Act claim challenging a product label that complies with the FDCA.

ARGUMENT

The Ninth Circuit Correctly Held That A Lanham Act Claim Cannot Be Used to Challenge A Product Label That Is Authorized By The Food, Drug, And Cosmetic Act, And Relevant Food And Drug Administration Regulations.

The issue before this Court involves the interaction between the FDCA and the Lanham Act. DRI members' national and multinational clients in the food and beverage industry rely on the system of national uniformity in labeling established by the specific requirements of the FDCA and NLEA. Allowing competitors to wield the general provisions of the Lanham Act as a weapon eliminates this safe harbor, is contrary to Congressional intent, and disregards

established rules for resolving conflicts between federal statutes. Private party suits also make it difficult for DRI members to advise their clients who are governed by the FDCA because standards will be unknowable in advance. Moreover, in DRI's experience, expanding the class of available plaintiffs results in increased litigation and concomitant costs. This Court should affirm the Ninth Circuit's ruling that Congress intended to preclude a private party from bringing a Lanham Act claim where a label is authorized by the specific provisions of the FDCA and the NLEA.

A. The specific provisions of the FDCA and NLEA provide guidance to manufacturers in developing proper labels.

When two federal statutes seemingly conflict, here the Lanham Act and the FDCA, courts must read them consistently whenever possible, *Kremer*, 456 U.S. at 468, and give precedence to the more specific statute, regardless of their temporal sequence, *Busic*, 446 U.S. at 406. See e.g., *Morton v. Mancari*, 417 U.S. 535, 547 (1974) (holding that the Equal Employment Opportunity Act of 1972, 42 U.S.C. § 2000e *et seq.*, did not negate employment preference for Indians expressly established by the Indian Reorganization Act of 1934, 25 U.S.C. § 461 *et seq.*). Similarly, the meaning of one statute may be affected by other acts, particularly where Congress has spoken subsequently and more specifically to the topic at hand. *Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000).

In this case, the FDCA and NLEA are more specific that the Lanham Act in determining whether a statement on a beverage label is false. DRI members

rely on these provisions to counsel their clients on developing proper labels. Allowing competitors to use the general provisions of the Lanham Act to destroy this safe harbor and thwart otherwise lawful marketing efforts is contrary to Congress's intent to create a system of national uniformity.

Section 43(a) of the Lanham Act is designed to combat false advertising of any product or service. It provides:

> [a]ny person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which . . . in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act.

15 U.S.C. § 1125(a)(1)(B).

The Lanham Act protects business entities against unfair competition. See 15 U.S.C. § 1127. Congress intended to allow false advertising suits by competitors "to stop the kind of unfair competition that consists of lying about goods or services, when it occurs in interstate commerce." *U-Haul Int'l, Inc. v. Jartran, Inc.*, 681 F.2d 1159, 1162 (9th Cir. 1982). See also *Proctor & Gamble Co. v. Haugen*, 222 F.3d 1262, 1272

(10th Cir. 2000), citing 5 McCarthy on Trademarks and Unfair Competition § 27:7 (4th ed.) ("As a general matter, the drafters and promoters of the original [Lanham Act], sought to create a general federal law of unfair competition to protect competing companies in the wake of the Supreme Court's decision in *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938), which was thought to have eliminated the existing body of federal unfair competition law."). To have standing in a suit for false advertising under § 1125(a), "a plaintiff must allege an injury to a commercial interest in reputation or sales." *Lexmark*, 12-873, 2014 WL 1168967 at *9. Thus, competitors are likely to use the Lanham Act to avenge perceived wrongs. See *TrafficSchool.com,* 653 F.3d at 827 ("[c]ompetitors vie for the same dollars from the same consumer group, and a misleading ad can upset their relative competitive positions).

Like the Lanham Act, the FDCA addresses false statements. But the FDCA, in conjunction with the NLEA, is directed more specifically to what is false or misleading on a food or beverage label, with an eye toward consumer protection as well as to ensuring efficiency in operations and marketing for manufacturers. DRI members' clients in the food and beverage industry rely on the specific provisions of these statutes to develop appropriate labels.

Under the FDCA, "[a] food shall be deemed to be misbranded" if "its labeling is false or misleading in any particular," 21 U.S.C. § 343(a)(1), or "[i]f any word, statement, or other information required by or under authority of this chapter to appear on the label or labeling is not prominently placed thereon with such conspicuousness . . and in such terms as to render it

likely to be read and understood by the ordinary individual under customary conditions of purchase and use." 21 U.S.C. § 343(f). A food is also misbranded unless it includes "the common or usual name of the food, if any there be." 21 U.S.C. § 343(i). FDA regulations further explicate specific rules for naming and labeling beverages that contain fruit or vegetable juice. See 21 C.F.R. § 102.33. Only the United States can bring an action to enforce these provisions, 21 U.S.C. § 337(a); the FDCA does not create a private right of action, *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 487 (1996).

Additionally, the NLEA preempts states from enacting different labeling requirements from those discussed above.

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce . . . . (3) any requirement for the labeling of food of the type required by section 343(b), 343(d), 343(f), 343(h), 343(i)(1), or 343(k) of this title that is not identical to the requirement of such section . . . .

21 U.S.C. § 343-1(a).

B. Congress intended to create a uniform national system of food and beverage labeling.

Together, the FDCA and NLEA protect consumers and provide guidance to the food and beverage manufacturers that DRI members represent. The FDCA was intended to "touch phases of the lives and

health of people which . . . are largely beyond self-protection." *62 Cases, More or Less, Each Containing Six Jars of Jam v. United States*, 340 U.S. 593, 596 (1951). "The statute is plain and direct. Its comprehensive terms condemn every statement, design, and device which may mislead or deceive. . . . The statute . . . was enacted to enable purchasers to buy food for what it really is." *United States v. Ninety-Five Barrels More or Less Alleged Apple Cider Vinegar*, 265 U.S. 438, 442-43 (1924). Misbranding, therefore, "was one of the chief evils Congress sought to stop." *62 Cases*, 340 U.S. at 596. It follows that the purpose of the labeling requirement is to inform and protect the ultimate consumer. *United States v. Kocmond*, 200 F.2d 370, 373-74 (7th Cir. 1952). See also 21 U.S.C § 341 (regulations are intended to "promote honesty and fair dealing in the interest of consumers").

Through the NLEA, Congress sought further to ensure a national uniform system in food labeling and was cognizant of the parallel benefit to manufacturers. Senator Mitchell observed that the amendment requires the FDA "to develop standardized nutrition labels for our foods . . . ." 136 Cong. Rec. S16607-02, 1990 WL 206648 (October 24, 1990). But this goal of national uniformity also allows the food industry to "market its products efficiently in all 50 States in a cost-effective manner." State Petitions Requesting Exemption from Federal Preemption, 58 Fed. Reg. 2462-01 (Jan. 6, 1993). Moreover, "the net benefits from national uniformity" ultimately help the consumer. *Id.*

Statements from other legislators emphasized national uniformity and recognized the benefit of such

a system to the twin goals of consumer protection and efficiency for manufactures. Rep Madigan explained that the NLEA "emphasizes disclosure of all valid and relevant information to the consumer, while providing the industry with uniformity of law in a number of important areas that will permit them to conduct their business of food distribution in an efficient and cost-effective manner." 136 Cong. Rec. H5836-01, 1990 WL 107635 (July 30, 1990). Senator Hatch agreed, and articulated amicus DRI's concern that any system that does not ensure uniformity burdens manufacturers by increasing the likelihood of litigation: "it is wrong to permit each of the 50 States to require manufacturers of 20,000 packaged food items to display different health and diet information on identical products sold throughout this country. And, it is wrong to burden the manufacturer with the fear of potentially 50 different lawsuits from 50 different State attorneys general, even if similar cases have been dismissed or settled." 136 Cong. Rec. S16607-02, 1990 WL 206648 (October 24, 1990). Rep. Waxman's comments echoed these concerns: "A national food processor understandably finds it difficult to comply with numerous conflicting and inconsistent State and local laws." 136 Cong. Rec. H5836-01, 1990 WL 107635 (July 30, 1990).

The situation would only be magnified if manufacturers were subjected to the whims of an infinite number of private parties enforcing their own notions of what constitutes an appropriate label. In DRI's experience, it is not out of the question for competitors to also use the Lanham act to thwart legitimate marketing efforts. DRI members' role in advising their clients as to an appropriate label thus

becomes more challenging and the potential for litigation increases exponentially. Litigation costs are ultimately passed on to the consumer and have ramifications on the economy as a whole. See e.g., Threat of Suits Spurs Hiring Cuts, Study Shows, 10 Alternatives to High Cost Litig. 74 (1992) ("State court decisions expanding employers' liability in wrongful termination cases are generating substantial costs beyond those directly related to litigation . . . [A]ggregate employment has dropped by as much as five percent in states where the theories are most liberally applied."). Allowing private party suits where labels are authorized by the FDCA undermines the system of uniformity created by Congress because standards are unknowable in advance, leaving DRI members unable to properly advise their clients. See e.g., *Elgin v. Dep't of Treasury*, 132 S. Ct. 2126, 2130 (2012) (Undermining the integrated scheme of review created by the Civil Service Reform Act "would reintroduce the very potential for inconsistent decisionmaking and duplicative judicial review that the CSRA was designed to avoid."). See also *Holloway v. Bristol-Myers Corp.*, 485 F.2d 986 (D.C. Cir. 1973) (Court held that private enforcement of the Trade Commission Act would be inconsistent with the legislative scheme established by Congress; the Federal Trade Commission's role in providing certainty and specificity to broad proscription of the Act would be endangered by private actions.)

C. Courts have recognized and upheld the system of uniformity intended by Congress.

DRI members' food and beverage manufacturer clients rely on the system of national uniformity for

food and beverage labeling created by the FDCA and NLEA. Lower courts have consistently recognized the safe harbor created by these statutes and have barred Lanham Act claims where labels and advertising are authorized by the specific provisions of the FDCA. The reasoning in the opinions is characterized as deference to Congress's decision to entrust food and drug labeling decisions to the FDA – which in essence recognizes Congress's intent to create a system of national uniformity in labeling.

In this case, the Ninth Circuit sought to give "as much effect to both [the FDCA and Lanham Act] as possible." *Pom Wonderful LLC v. Coca-Cola Co.*, 679 F.3d 1170, 1176 (9th Cir. 2012), quoting *Schering-Plough Healthcare Prods., Inc. v. Schwarz Pharma, Inc.*, 586 F.3d 500, 508 (7th Cir. 2009). The court determined that, where a label is authorized by the FDCA, it is not proper for a private party to bring a Lanham Act claim. "[C]ourts must generally prevent private parties from undermining, through private litigation, the FDA's considered judgments." *Id.* at 1178. As the Ninth Circuit recognized, the overriding consideration here is that Congress has entrusted the FDA with interpreting and enforcing the FDCA. *Id.* at 1175.

Other courts have articulated rules consistent with the Ninth Circuit's holding when construing the FDCA in conjunction with the Lanham Act, recognizing the safe harbor created by the FDCA. In the context of pharmaceuticals, "courts have generally rejected Lanham Act claims based on advertisements that merely repeat labeling information that has been approved by the FDA." *Mylan Pharm., Inc. v. Proctor*

& Gamble Co., 443 F. Supp. 2d 453, 460 (S.D.N.Y. 2006), citing *Cytyc Corp. v. Neuromedical Sys., Inc.*, 12 F.Supp.2d 296, 301 (S.D.N.Y.1998) ("representations ... that comport substantively with statements approved as accurate by the FDA cannot supply the basis for [Lanham Act] claims") and *SmithKline Beecham Consumer Healthcare, L.P. v. Johnson & Johnson-Merck Consumer Pharm. Co., Inc.*, 1996 WL 280810, *13 (S.D.N.Y. May 24, 1996) (denying injunction against defendant for advertising claims based on FDA-approved packaging and labeling).

In *Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934, 937 (8th Cir. 2005), by contrast, the Court *allowed* a Lanham Act challenge asserting that the defendant falsely advertised that a product had been approved by the FDA for a number of uses for which it had not. This was plainly a false statement that was not relevant to whether the label otherwise complied with the specific requirements of the FDCA. The court thus found that deference to the FDA was not required in that case because the resolution of the issue did not require "expert consideration and uniformity of resolution." *Id.* at 939, citing *United States v. McDonnell Douglas Corp.*, 751 F.2d 220, 224 (8th Cir. 1984). Rather, a plainly false statement is actionable under the Lanham Act because it affects fairness in competition.

Courts have also recognized that barring private parties from bringing Lanham Act claims against a product label that complies with the FDCA respects the fact that, while the Lanham Act and the FDCA both share the common purpose of preventing false statements, the FDCA is directed more specifically to

what is false or misleading on a food or beverage label with an eye toward consumer protection. In *Am. Home Products Corp. v. Johnson & Johnson*, 672 F. Supp. 135 (S.D.N.Y. 1987), the court found that FDA approval of a label used by the manufacturer of aspirin-containing products was a complete defense to a competitor's Lanham Act claim, which alleged that the defendant falsely advertised the superior safety and efficacy of its product but failed to warn of the risk of contracting Reye Syndrome. *Id.* at 144. The FDA had not required such a warning at the time. Thus the situation is analogous to Petitioner here demanding more or different regulations on how images and words must appear on the juice label.

In *Am. Home Products Corp.*, the plaintiff relied on several state law product liability cases which held that "a consumer who is injured as a result of using a dangerous product may recover damages against the manufacturer," even where a government agency had approved the products as safe. 672 F. Supp. at 142. But the court found that "[r]ulings in product liability cases are simply not controlling in a Lanham Act action," because the Lanham Act was not designed for consumer protection but rather the protection of " 'persons engaged in commerce against unfair competition.' "*Id.* at 143, quoting *Colligan v. Activities Club of New York, Ltd.*, 442 F.2d 686, 691-92 (2d Cir. 1971).

Accordingly, where the FDCA and NLEA are more specific that the Lanham Act in determining whether a statement on a beverage label is false, barring private parties from bringing Lanham Act claims against a product label that is authorized by the FDCA is

consistent with the purposes of the two federal statutes and with Congress's intent to create a national system of uniformity in labeling to protect consumers and allow manufactures to efficiently market in all 50 states. This Court should affirm the Ninth Circuit and hold that a private party cannot bring a Lanham Act claim challenging a product label that is authorized by the FDCA.

CONCLUSION

For the foregoing reasons, the decision of the court of appeals should be affirmed.

Respectfully submitted,

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AMICUS CURIAE BRIEF

RECORD AND BRIEFS

Supreme Court, U.S.
FILED
APR 2 2014
OFFICE OF THE CLERK
SUPREME COURT, U.S.

No. 12-761

IN THE

Supreme Court of the United States

POM WONDERFUL LLC,

Petitioner,

v.

THE COCA-COLA COMPANY,

Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF OF DR. MICHAEL FRIEDMAN, FORMER ACTING COMMISSIONER AND LEAD DEPUTY COMMISSIONER FOR THE UNITED STATES FOOD AND DRUG ADMINISTRATION AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

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INTEREST OF *AMICUS*

Dr. Michael Friedman has spent his career as an advocate for science in the service of the public health and welfare.[1] He is a former Acting Commissioner and Lead Deputy Commissioner at the United States Food and Drug Administration ("FDA") (1997-1998). Prior to his service with the FDA, Dr. Friedman, a board-certified medical oncologist, worked at the National Cancer Institute in various capacities for over a decade, before which he was on the faculty at the University of California, San Francisco Medical School, leading the institution's research on cancer treatment and education. From 2003 until January 2014, when he assumed emeritus status, Dr. Friedman was President and Chief Executive Officer of City of Hope, a comprehensive cancer research and treatment center. He was a Rear Admiral and served as Assistant Surgeon General in the U.S. Public Health Service. He has received numerous awards and citations throughout his career of public service, including the Surgeon General's Medallion, the DHHS Award for Superior Service, and the PHS Distinguished Service Medal.

Dr. Friedman participates in the editorial boards of many peer-reviewed journals, and he has also published 99 scholarly articles and authored 57 book chapters. He has been appointed to numerous boards of directors and advisory boards, including the Board of Trustees of

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1. This brief has been filed with the written consent of the parties, which is on file with the Clerk of the Court. Pursuant to Rule 37.6, counsel for amicus affirms that no counsel for a party authored this brief in whole or in part, nor did any person or entity, other than amicus or his counsel, make a monetary contribution to the preparation or submission of this brief.

Tulane University; the Board of Governors of the Armed Forces Institute of Pathology; the Boards of Directors of Smith & Nephew Corporation, the Celgene Corporation, the Mannkind Corporation and the Independent Citizens' Oversight Committee of the California Stem Cell Initiative; the Harvard Medical School Industry Advisory Board; and the Harvard University John F. Kennedy School of Government Dean's Council.

SUMMARY OF ARGUMENT

In areas where the FDA has engaged in formal notice-and-comment rulemaking, carefully balancing the interests of consumers, regulators, scientists, and industry, private litigation should not be permitted to upset the FDA's detailed regulatory scheme and create a patchwork of inconsistent rules and precedents. In this action, the Ninth Circuit and the Central District of California correctly held that a private litigant's Lanham Act claim, impermissibly challenging the labeling of a juice product that complied with the FDA regulations permitting that labeling, should be barred. The FDA's regulatory scheme, which balances competing interests and is informed by scientific research and consumer expectations, is entitled to deference, and this Court should not enable private litigants to undermine the agency's considered judgments and actions.

Before the enactment of the Nutrition Labeling and Education Act of 1990 ("NLEA")[2], food and beverage labeling was a confusing hodgepodge that served neither

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2. The NLEA amended the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*

consumers nor manufacturers. In passing the NLEA, Congress sought to bring order to this chaos by tasking the FDA with the creation of a national labeling standard. Pursuant to this statutory grant of authority, the FDA embarked on a formal notice and comment procedure that resulted in a detailed regulatory scheme embodying the FDA's judgment as to what would, and would not, mislead consumers.

Private litigation, substituting the judgment of self-interested commercial competitors for that of the FDA in a myriad of private lawsuits, and the judicial decisions arising from those individual actions, would lead to standards more likely to mislead consumers than the FDA's uniform regulations. Those regulations, based on scientific expertise and substantial public comment, permit industry and consumers to rely on settled expectations in creating and reading food labels, just as Congress intended in enacting the NLEA. The FDA's continuing enforcement actions on food labeling are taken seriously by industry and by consumers, and have caused manufacturers to make changes to misleading labels. In areas where the FDA has chosen to promulgate such rules and take such actions, the application of consistent, clear, objective, and scientific standards best serves the public interest. For these reasons, the judgment below should be affirmed.

ARGUMENT

I. THE FDA'S CONCLUSION THAT CERTAIN FOOD LABELING IS NOT MISLEADING IS ENTITLED TO DEFERENCE

This Court has long recognized that formal rulemaking relying on agency expertise, in making policy in the gaps purposely left by Congress in an enabling statute, is fundamentally entitled to respect. *See, e.g., Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 165 (2007) ("The subject matter of the regulation in question concerns a matter in respect to which the agency is expert, and it concerns an interstitial matter, . . . the details of which, as we said, Congress entrusted the agency to work out. The Department focused fully upon the matter in question. It gave notice, it proposed regulations, it received public comment, and it issued final regulations in light of that comment.") (citing *United States v. Mead Corp.*, 533 U.S. 218, 230 (2001)); *see also Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 843-844 (1984); *Young v. Cmty. Nutrition Inst.*, 476 U.S. 974, 981 (1986) (holding that FDA's interpretation of FDCA provision was "sufficiently rational to preclude a court from substituting its judgment for that of the FDA").

In 1990, Congress passed the NLEA, to regulate the nutrition labeling of food and beverages under the FDCA. *See* Nutrition Labeling and Education Act of 1990, Pub. L. No. 101-535, 104 Stat. 2353 (1990). The FDCA prohibits misbranded foods. *See* 21 U.S.C. §§ 331, 343.[3] When

3. Misbranded food includes: (1) labels which are "false or misleading" (21 U.S.C. § 343(a)); (2) labels on which required

Congress passed the NLEA, it elaborated two goals: First, to "make sense of the confusing array of nutrition labels" confronting consumers (*see* 136 Cong. Rec. H5836-01 (July 30, 1990) (statement of Rep. Waxman)); and second, to ease the burden on manufacturers by creating a uniform regulatory scheme (*see* 136 Cong. Rec. S16607-02 (Oct. 24, 1990) (statement of Sen. Hatch)).

Pursuant to the NLEA, in July 1991, the FDA issued proposed rules regarding the naming and labeling of multi-juice beverages and sought comments. 56 Fed. Reg. 30452-01 (July 2, 1991). As the District Court noted, the FDA was particularly sensitive to the question of how best to label multiple-juice beverages which often "contain only a small amount of a highly flavored, expensive juice." Pet. App. 45a (quoting 56 Fed. Reg. 30452-01, 30455 (July 2, 1991)). Indeed, the FDA explained that "the very nature of these 'blends,' mixtures of several juices, with only one or two minor juices giving them flavor, makes them difficult to label." 56 Fed. Reg. 30452-01 at 30462. In January 1993, the FDA issued its final rules on the basis of "over 200 responses," each containing one or more comments, from "a wide range of sources, including consumers, consumer organizations, professional associations, State and local government agencies, manufacturers, and trade associations." 58 Fed. Reg. 2897-01, 2897 (Jan. 6, 1993). This deliberate rulemaking embodied the FDA's expert judgment on how best to create a uniform national standard that would "prevent misleading labels on multiple-juice beverages." *Id.* at 2920.

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statements are not prominently and conspicuously placed as to render it likely to be read and understood by ordinary individuals under customary conditions (21 U.S.C. § 343(f)); and (3) labeling that fails to disclose "the common or usual name of the food", if one exists (21 U.S.C. § 343(i)).

As federal courts consistently acknowledge, the FDA is uniquely qualified to make these determinations. *See, e.g., Schering-Plough Healthcare Products, Inc. v. Schwarz Pharma, Inc.*, 586 F.3d 500, 509 (7th Cir. 2009) (noting that FDA "has more experience with consumers' understanding of drug labels than judges do"); *see also Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 231 (3d Cir. 1990) ("We decline to find and do not believe that the district court had to find, either 'as a matter of common sense' or 'normal English,' that which the FDA, with all of its scientific expertise, has yet to determine."). The FDA's rules sought to achieve a careful balance among various competing stakeholders. *See* 58 Fed. Reg. 2897-01 at 2920 ("These provisions are intended to provide manufacturers with flexibility for labeling products while providing consumers with information that they need to determine the nature of the product.").

In this private litigation, Petitioner Pom Wonderful LLC ("Pom") asserted a claim against The Coca Cola Company ("Coca Cola") under the Lanham Act (15 U.S.C. §§ 1051 *et seq.*), asserting that the name and labeling of Coca Cola's "Pomegranate Blueberry Flavored Blend of 5 Juices" were misleading because, although flavored with pomegranate and blueberry, the juice was allegedly predominantly composed of apple and grape juice. Pet. App. 3a. The District Court and the Ninth Circuit both held that the beverage's name and labeling were permitted by FDA regulations. Pet. App. 9a, 12a, 62a, 64a. As the Ninth Circuit recognized, permitting Pom's Lanham Act claim to proceed would thus "undermine the FDA's regulations and expert judgments." Pet. App. 10a. Noting that regulation of juice labeling has been entrusted to the FDA by Congress, the Ninth Circuit observed that "the

FDA has apparently not taken a view on whether Coca-Cola's labeling misleads consumers – even though it has acted extensively and carefully in this field." Pet. App. 11a-12a. Under these circumstances, where the FDA has promulgated detailed regulations specifically addressing the question whether a multi-juice beverage's name and label are false or misleading, the lower courts properly decided not to second-guess the FDA's judgment.

The FDA's deliberative process in arriving at its detailed multi-fruit beverage labeling regulatory scheme, through formal notice-and-comment rulemaking, reveals the flaw in the argument of Petitioner's amicus Dr. Donald Kennedy, when he contends, "The FDCA merely sets a 'floor' for regulation of labels on which other laws can build." Kennedy Br. 2, 4 (citing *Wyeth v. Levine*, 555 U.S. 555, 577-78 (2009)). Respectfully, Dr. Kennedy's reliance on *Wyeth*'s state-law preemption analysis is misplaced.

In *Wyeth*, this Court affirmed a state-law tort judgment, rejecting petitioner's implied preemption arguments, notwithstanding the FDA's approval of a specific pharmaceutical manufacturer's warning label for a specific medication, but the Court expressly distinguished the FDA's approval of a specific prescription drug's warning label from the agency's formal regulations. *See Wyeth v. Levine*, 555 U.S. 555, 580 (2009) ("By contrast, we have no occasion in this case to consider the pre-emptive effect of a specific agency regulation bearing the force of law."). Indeed, Justice Breyer's concurring opinion in *Wyeth* noted this distinction, and recognized that the FDA "may seek to embody those determinations in lawful specific regulations describing, for example, when labeling requirements serve as a ceiling as well as

a floor." *See Wyeth*, 555 U.S. at 582 ("And it is possible that such determinations would have pre-emptive effect.") (Breyer, J., concurring).[4] The District Court below adopted a similar analysis. *See* Pet. App. 62a ("The FDA has directly spoken on the issues that form the basis of Pom's Lanham Act claim against the naming and labeling of the Juice, and has therefore, reached a conclusion as to what is permissible. *See* 21 C.F.R. §§ 102.33(c), (d).").

II. THE PUBLIC GOOD IS BEST SERVED BY CONSISTENT, SCIENTIFIC STANDARDS, UNIFORMLY ENFORCED BY THE FDA.

As Congress recognized in passing the NLEA, the public good is best served by a consistent, clear, rigorous, scientific standard of food and beverage labeling, uniformly enforced by the FDA. Permitting ad hoc challenges by competitors would result in just the opposite. Moreover, allowing rules to be determined by the adjudication of private claims among commercially-motivated parties could very easily result in a system that is actually more misleading to consumers. Not surprisingly, Congress has provided for no private cause of action under the FDCA, reserving enforcement powers exclusively to the United States government. *See* 21 U.S.C. § 337(a).

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4. Of course, unlike in *Wyeth*, the instant appeal does not implicate state law preemption, and in any event Congress expressly preempted inconsistent state law when it enacted the NLEA. *See* NLEA § 6(a)(3) (codified in part at 21 U.S.C. § 343-1(a)(3)). By contrast, as this Court noted in *Wyeth*, Congress expressly declined to enact an express state-law preemption provision for prescription drug labeling. *See* 555 U.S. at 574-75.

Private litigation would disrupt the very uniformity sought by Congress in enacting the NLEA and subject manufacturers to an inefficient hodgepodge of judge-made rules across the fifty states. *See* 136 Cong. Rec. S16607-02 (Oct. 24, 1990) (statement of Sen. Hatch) ("[I]t is wrong to burden the manufacturer with the fear of potentially 50 different lawsuits from 50 different State attorneys general, even if similar cases have been dismissed or settled."). Here, permitting private Lanham Act claims against food labels that comply with the FDA's specific labeling requirements would frustrate Congress's stated intention to create a national, uniform standard. A lack of uniformity would also be detrimental to consumers, whose ability to comprehend product names and labeling is facilitated through the use of standardized conventions, such as the specific meaning of the word "flavored" here, *see* 21 C.F.R. § 102.33(b), (d),[5] and to industry, who require bright-line rules in making food and beverage product investment and marketing decisions as well as formulating labels. *See* 58 Fed. Reg. 2462-01, 2462 (Jan. 6, 1993) ("FDA acknowledges that some stringent State laws will be preempted by less restrictive Federal regulations. However, one of the goals of the 1990 [NLEA] is national uniformity in certain aspects of food labeling, so that the

5. *See* 58 Fed. Reg. 2897-01 at 2921 ("The agency believes that using the term 'flavor' with the name of the characterizing juice will inform the consumer that the juice is present in an amount sufficient to flavor the beverage but will not imply that the content of that juice is greater than is actually the case."). The FDA's decision to adopt such standardized terminology, after it carefully considered over 200 public comments, is itself subject to deference. *See id.* at 2900 ("The agency believes that this approach will adequately deal with the kinds of misleading labeling discussed in the comments from consumer groups.").

food industry can market its products efficiently in all 50 States in a cost-effective manner.") (citation omitted); *cf.* 136 Cong. Rec. H5836-01 (July 30, 1990) (statement of Rep. Bruce) (noting the high cost "to accommodate any one State with unique food labeling requirements").

Moreover, business competitors striving for commercial advantage lack the FDA's dispassionate scientific expertise or consideration for the consumer, and are not better positioned than the FDA to police food and beverage labeling. It is simply wishful thinking to assume that private enforcement by competitors focused on their own pocketbook — not on consumers' best interests — will result in a scheme that is beneficial to consumers. Indeed, the present case is instructive. Pom has asserted that Coca Cola ought to have named its product "Apple Grape" (*see* Pet. App. 60a), but naming a beverage for certain fruits, when it has the flavoring of, and tastes like, different fruits, would clearly be misleading and confusing to consumers. The FDA's regulations in this context specifically resolve this problem, permitting manufacturers to use a product name that "identifies the juice that provides the characterizing flavor and specifically shows that that juice is used to flavor the product." 58 Fed. Reg. 2897-01 at 2921.

Even more instructive, Pom has itself received a warning letter from the FDA regarding its product labeling, and it has been involved in protracted litigation with the Federal Trade Commission regarding claimed health benefits. *See In the Matter of Pom Wonderful LLC and Roll Int'l Corp.*, FTC File No. 082-3122, Docket No. 9344 (Jan. 16, 2013); *see also* Letter from Roberta C. Wagner, FDA Director of Compliance, to Matt

Tupper, President, Pom Wonderful LLC (Feb. 23, 2010), *available at* http://www.fda.gov/iceci/enforcementactions/warningletters/ucm202785.htm. Without any comment on the merits of those allegations, these circumstances show how any particular business competitor's interests may not always coincide with consumer welfare — and no one should expect otherwise.

By contrast, scientific research and investigation of food components and health factors is crucial to the FDA's mission. For example, the FDA is deeply committed to expanding its expertise in how consumers make sense of labels. In July 2013, the FDA proposed studies "designed to assist the agency in developing labeling information to help consumers make informed dietary decisions." *See* Proposed Data Collection Abstract, *Eye Tracking Experimental Studies to Explore Consumer Use of Food Labeling Information and Consumer Response to Online Surveys*, OMB Control No. 0910-0761 (Jul. 16, 2013), *available at* http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201307-0910-003#section2_anchor. These studies will use "state-of-the-art eye-tracking equipment and techniques" to "collect data on how consumers view and use labeling information." *Id.*[6] As available information and consumer habits change, the FDA updates the regulatory structure for food and beverage labeling. As recently as March 3, 2014, the FDA issued a proposed rule to amend its food labeling regulations to provide updated nutrition information. *See* 79 Fed. Reg. 11879, 11880 (March 3, 2014). This is

6. On March 17, 2017, FDA announced that the Office of Management and Budget had approved these studies. 79 Fed. Reg. 14713-03, 14713 (March 17, 2014).

hardly an area where Congress delegated authority and the agency failed to act.

Nor has the FDA neglected the enforcement imperative. For example, in February 2010, the FDA issued warning letters to 17 different companies, including Nestle, Gerber, and Pom itself. *See* Layton, L., *FDA Warns 17 Food Companies of Misleading Claims on Labels*, The Washington Post (March 4, 2010), *available at* http://www.washingtonpost.com/wp-dyn/content/article/2010/03/03/AR2010030303119_pf.html. In connection with these warning letters, Dr. Margaret A. Hamburg, Commissioner of Food and Drugs, released an open letter to the industry stating that "improving the scientific accuracy and usefulness of food labeling" was one of her priorities as Commissioner. Dr. Hamburg also noted the desire within the industry for a "level playing field" and her own belief that "FDA should provide as clear and consistent guidance as possible about food labeling claims." Letter from Dr. Margaret A. Hamburg, Commissioner of Food and Drugs, to Industry (March 3, 2010), *available at* http://www.fda.gov/Food/IngredientsPackagingLabeling/LabelingNutrition/ucm202733.htm.

These warning letters are not trivial matters; companies take them seriously. For example, on February 22, 2010, the FDA issued a warning letter to Diamond Food, Inc. ("Diamond"), alleging that their walnuts were misbranded as a result of unauthorized health claims. *See* Letter from Roberta Wagner, FDA Director of Compliance, to Michael J. Mendes, President and Chief Executive, Diamond Food, Inc. (Feb. 22, 2010), *available at* http://www.fda.gov/iceci/enforcementactions/warningletters/ucm202825.htm. In response, Diamond

promptly issued a press release expressing its intent to work with the FDA and make any required changes "expeditiously and with minimal expense." Press Release, Diamond Foods, Inc., Statement from Diamond Foods (March 3, 2010), *available at* http://investor.diamondfoods.com/phoenix.zhtml?c=189398&p=irol-newsArticle&ID=1398458&highlight. In this case, and many others, the system worked fairly and efficiently, without the attendant costs to parties and strain on the already burdened court system that private litigation would have entailed. The FDA's warning letters' success in motivating voluntary compliance by manufacturers is a vital and real component of the FDA's enforcement arsenal.

Although it is true that the scope of Congress's delegation to the FDA is enormous, and the resources of the FDA are finite, those truths do not alter the fundamental public policy principle that the agency is the appropriate place for specific labeling regulations to be promulgated and enforced. While there may be resource constraints, enforcement responsibility should nevertheless rest with FDA — the agency, not private parties, is the only instrument for consistent, unbiased, fair, uniform enforcement based on scientific principles.

CONCLUSION

The judgment below should be affirmed.

Respectfully submitted,

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Dated: April 2, 2014

AMICUS CURIAE BRIEF

RECORD
AND
BRIEFS

Supreme Court, U.S.
FILED
MAR - 3 2014
OFFICE OF THE CLERK

No. 12-761

IN THE

Supreme Court of the United States

POM WONDERFUL LLC,

Petitioner,

v.

THE COCA-COLA COMPANY,

Respondent.

On Writ of Certiorari
to the United States Court of Appeals
for the Ninth Circuit

BRIEF FOR THE GENERIC PHARMACEUTICAL ASSOCIATION AS AMICUS CURIAE SUPPORTING NEITHER PARTY

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March 3, 2014

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BRIEF FOR THE GENERIC PHARMACEUTICAL ASSOCIATION AS AMICUS CURIAE SUPPORTING NEITHER PARTY

INTEREST OF THE AMICUS CURIAE[1]

The Generic Pharmaceutical Association (GPhA) is a nonprofit, voluntary association representing nearly 100 manufacturers and distributors of finished generic pharmaceutical products, manufacturers and distributors of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic pharmaceutical industry. GPhA's members provide American consumers with generic drugs that are just as safe and effective as their brand-name counterparts, but substantially less expensive. GPhA members' products account for roughly 80% of all prescriptions dispensed in the United States but only 27% of the money spent on prescriptions. In this way, the products sold by GPhA members save consumers nearly $200 billion each year. GPhA's core mission is to improve the lives of consumers by providing timely access to affordable pharmaceuticals. GPhA regularly participates in litigation as *amicus curiae*, taking legal positions that are adopted by GPhA's Board of Directors and reflect the position of GPhA as an organization. Most recently, GPhA participated as *amicus curiae* on the merits in

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[1] All parties have consented to the filing of this brief. Letters reflecting the parties' consent are being lodged with the Clerk. No counsel for a party authored any portion of this brief. No party and no other entity, except *amicus*, its members, and its counsel, made any monetary contribution toward the preparation or submission of this brief.

this Court in *FTC v. Actavis, Inc.*, No. 12-416; *Mut. Pharm. Co. v. Bartlett*, No. 12-142; and *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, No. 10-844.

Generic drug companies are periodically targeted by brand-name competitors seeking to use broad, general federal statutes, including the Lanham Act, to thwart generic competition even once a generic drug has been approved by the Food and Drug Administration (FDA) pursuant to the Federal Food, Drug, and Cosmetic Act (FDCA). *See, e.g., Wyeth v. Sun Pharm. Indus., Ltd.*, No. 09-11726, 2010 WL 746394 (E.D. Mich. Mar. 2, 2010) (Lanham Act); *see also SmithKline Beecham Consumer Healthcare, L.P. v. Watson Pharm., Inc.*, 211 F.3d 21 (2d Cir. 2000) (Copyright Act). Federal courts have generally rejected such attempts to circumvent FDA approval decisions.

This case concerns the intersection between the Lanham Act and one particular area of the FDCA, food labeling. The FDCA contains a number of different regulatory structures, *e.g.*, for food, drugs, and medical devices. GPhA files this brief as *amicus curiae* to highlight the need to distinguish carefully among the relevant aspects of the FDCA: while a number of the elements on which respondent Coca-Cola and the court below relied are common to all regulatory structures under the FDCA, petitioner Pom relies principally on aspects of the FDCA that are specific to food labeling. In its decision, this Court should be cognizant of the differences. Even if petitioner is allowed to proceed with certain aspects of its claim, the Court should make clear that such a decision does not license second-guessing explicit FDA approvals, and in particular FDA approvals un-

der the agency's authority to review and approve the licensing, labeling, and marketing of pharmaceuticals.

SUMMARY OF ARGUMENT

The FDCA expressly forbids private enforcement of its requirements. *See* 21 U.S.C. § 337(a). As this Court has recognized, the statute is to "be enforced exclusively by the Federal Government." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001). Accepting the broadest version of petitioner's argument would render that proposition a nullity, because virtually every misbranding claim a private party might wish to bring under the FDCA can be repackaged as a "false or misleading advertising" claim under the Lanham Act. That reading is unsustainable.

While the Lanham Act may have a valid role to play with respect to FDCA-regulated products, it cannot be used to second-guess the FDA directly. That second-guessing takes two principal forms: contending that a particular label, advertisement, or similar communication is "false" or "misleading" when the FDA has specifically reviewed the communication and determined that it is neither, and contending that a particular statement in labeling, advertising, or similar communication is false when the FDA has specifically determined that it is true. In those contexts, Congress has given primacy to the FDA and specified that private plaintiffs may not substitute their own judgment under the FDCA.

A number of petitioner's arguments are drawn not from the FDCA as a whole, but from aspects of the FDCA that are specific to food-labeling regulation.

Should this Court adopt any of those arguments, it is essential that the Court make clear that the analysis would differ under other subparts of the FDCA, such as those regulating prescription drugs or medical devices. Petitioner contends that the FDA did not review respondent's juice label individually, and so did not pass on the question whether the label as a whole (as opposed to the name) was misleading. But the FDA does review other products, such as drugs and devices, in great depth, including to ensure that their labeling and, in some cases, other advertising is not false or misleading. And petitioner repeatedly emphasizes that Congress has saved state-law suits *over food labeling* from preemption, inviting the Court to infer that Congress must therefore have had no problem with a Lanham Act action in this context as well. To the extent that inference is a valid one, by its own terms it does not extend beyond the food-labeling context. Other parts of the FDCA, such as the one relating to generic-drug labeling, have quite different preemption regimes. To the extent this Court holds that Lanham Act claims can coexist with some portion of the FDCA, this Court should be precise in identifying *which* portion of the FDCA, and what aspects of that portion inform the preclusion analysis.

To say the least, allowing a Lanham Act claim to proceed on these facts would not authorize a Lanham Act claim that depends on second-guessing the FDA in a context where Congress has done nothing to signal tolerance of private lawsuits.

ARGUMENT

The Lanham Act imposes strict liability on defendants for making statements in advertising that a jury finds to be either "false" or "misleading." But when that statement has been approved by the FDA pursuant to its responsibilities under the FDCA, a lay jury cannot be allowed to second-guess the agency's expert determinations—by holding that a statement is false when the FDA says it is true, or that labeling or advertising is misleading when the FDA says it is not. Many of the FDA's decisions are judicially reviewable, under a deferential standard that takes due account of the agency's expertise. A litigant cannot dodge the principle of agency deference by using the Lanham Act to litigate the accuracy of the agency's determinations.

I. Plaintiffs Cannot Use the Lanham Act To Undo Congress's Decision To Bar Private Actions Enforcing the FDCA

This case involves the Lanham Act's intersection with a key provision of the FDCA: 21 U.S.C. § 337(a), which "leaves no doubt" that the FDCA is to "be enforced exclusively by the Federal Government." *Buckman*, 531 U.S. at 349 n.4, 352. Section 337(a) provides that "proceedings for the enforcement . . . of [the FDCA] shall be by and in the name of the United States," not in the name of private individuals. Following *Buckman*, it is universally understood that the FDCA "forbids private rights of action,"[2] whether for food, drugs, devices, or cosmetics.

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[2] *E.g.*, *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 924 (9th Cir. 2010); *accord, e.g.*, *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 236

Congress's omission of a private right of action was no accident. To the contrary, Congress entertained the possibility of allowing private parties to enforce the FDCA themselves, but it ultimately did not include such a provision in the FDCA. *See, e.g.*, *Bailey v. Johnson*, 48 F.3d 965, 967 (6th Cir. 1995) (citing legislative history).

Rather, Congress provided that violations of the FDCA's myriad requirements, from obtaining a required FDA approval to advertising truthfully, would be punished by the federal government itself. FDCA violations involving drugs and devices can be remedied by injunction, 21 U.S.C. § 332(a), and by criminal prosecution, *id.* § 333(a). And *only* the federal government can initiate those proceedings.[3]

For instance, only the government may enforce the prohibition on "misbranding" and seek to punish those who violate it. *See id.* § 331(a), (b). A product can be "misbranded" for a number of reasons, many of them relating to how the product is labeled. Food, for example, is misbranded if "its labeling is false or misleading in any particular." *Id.* § 343(a)(1). Similarly, in the drug and device context, misbranding includes both using "labeling [that] is false or misleading in any particular" and advertising a prescription drug in a manner that is not "true" in every particular that FDA requires to be included in the ad.

(6th Cir. 2000); *Bailey v. Johnson*, 48 F.3d 965, 967 (6th Cir. 1995) (citing cases); *PDK Labs, Inc. v. Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997).

[3] By contrast, violations of the rules for food advertising carry no criminal or civil penalties. *See* 21 U.S.C. § 333(d). In addition, state governments may under some circumstances bring suit to enforce the FDCA. *Id.* § 337(b).

Id. § 352 (a), (n). Many products also cannot be sold without the FDA's approval, and for both drugs and devices, the approval process considers whether the proposed labeling is "false or misleading." *Id.* §§ 355(d)(7), 360e(d)(1)(A).

A. The FDCA Bars Lawsuits Second-Guessing the Agency's Determination That Labeling Is Not False or Misleading

Section 337(a) precludes a private party from bringing a lawsuit alleging that a prescription drug is labeled in a false or misleading way, and therefore that it is misbranded or that it is being marketed in violation of the FDCA notwithstanding the FDA's approval, because its labeling is false or misleading. And that prohibition goes beyond lawsuits seeking to invoke a (nonexistent) private right of action under the FDCA. As this Court held in *Buckman*, the FDCA itself precludes a State from creating a cause of action based on violation of the FDCA. 531 U.S. at 352-53. Such state causes of action are impermissible because they exert an "extraneous pull" on the FDA's enforcement discretion. *Id.* It stands to reason that Congress would not have wanted to allow a *federal* cause of action to exert precisely the same "extraneous pull."

Yet that is precisely what a Lanham Act cause of action does when it overlaps with the FDCA. A private lawsuit challenging the labeling of a food, drug, or device as "false" or "misleading" under the Lanham Act, when the FDA has approved that specific labeling as *not* false or misleading under the FDCA, undermines Congress's judgment that the federal

government enforce the FDCA's requirements and prohibitions.

For that reason, the court of appeals was correct to hold, in line with numerous other appellate decisions, "that the FDCA limits claims under the Lanham Act, . . . because allowing such a suit would undermine Congress's decision to limit enforcement of the FDCA to the federal government." Pet. App. 6a-7a. The specificity with which Congress declared that private parties may not enforce the FDCA in court is enough to "preclude a construction of the [Lanham Act] that permits the instant suit." *Argentine Republic v. Amerada Hess Shipping Corp.*, 488 U.S. 428, 438 (1989).

Challenging that holding, petitioner misapplies this Court's cases concerning how to reconcile two overlapping, potentially contradictory federal statutes. Petitioner has repeatedly contended that the court of appeals failed to follow the principle that each of the two statutes must be given effect. *E.g.*, Pet'r Br. 20-21; Pet'r Cert.-Stage Supp. Br. 6. But in the strongest form of its argument, petitioner appears to insist that the Lanham Act cannot yield to the FDCA *at all*. *See* Pet'r Br. 24. Nothing in this Court's cases requires that the Lanham Act be given the maximum possible effect in all cases, heedless of the potential impact on the FDCA. Rather, given the specific prohibition on private enforcement in Section 337(a), the statutes are easily construed *in pari materia* so that the Lanham Act does not apply to statements whose allegedly "false" or "misleading" nature has already been reviewed by the FDA. *See, e.g., Crawford Fitting Co. v. J.T. Gibbons, Inc.*, 482 U.S. 437, 445 (1987). "To eliminate the contradic-

tion" between the specific FDCA and the general Lanham Act, "the specific provision is construed as an exception to the general one." *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 132 S. Ct. 2065, 2071 (2012).

That construction does not impliedly repeal the Lanham Act, or deprive it of effect; the Lanham Act "of course has the same effect . . . with respect to" claims not precluded by the FDCA, an overwhelming majority. *Amerada Hess*, 488 U.S. at 438. By contrast, Section 337(a) does *not* have the same effect if the Lanham Act may be used to circumvent it. A statute specifying that there be *no* private enforcement is rendered ineffective by *any* private enforcement. Put another way, Congress has not insisted that everyone must have a Lanham Act remedy, but it *has* insisted that no one may bring a private lawsuit to enforce the FDCA.

B. The FDCA Bars Lawsuits Seeking To Declare False What the Agency Has Declared True

The same rationale applies with equal force where the FDA's decision does not turn on the statutory terms "false" or "misleading," but where the Lanham Act cause of action seeks to declare "false"—and actionable—a proposition that the agency has specifically declared to be true. *See, e.g.*, *Wyeth*, 2010 WL 746394, at *4-5 (contention that generic drug was not bioequivalent to brand-name drug). As the government correctly states, a Lanham Act claim is precluded "if that claim rest[s] on grounds that would conflict with a determination underlying the agency's approval." U.S. Cert.-Stage Amicus Br. 16. The

agency is in a far superior position to make the judgments of scientific fact that underlie the approvals of specific products. And regulated parties understandably place significant, investment-backed reliance on the FDA's approval decisions. To the extent those decisions are challenged, it must be under the deferential standard of the Administrative Procedure Act, not before a jury being asked to award treble damages under the Lanham Act, *see* 15 U.S.C. § 1117(a).

The sort of scientific judgment made by the FDA is not suitable for second-guessing in a Lanham Act case. The Lanham Act allows lay juries to decide the truth or falsity of statements in advertising that rest on complex science. "If the advertising involves medical, scientific, or technical matters, expert witnesses will be necessary to unravel truth from falsity." 5 J. Thomas McCarthy, *McCarthy on Trademarks and Unfair Competition* § 27:56, at 27-138 (4th ed. 2013). Where there is competing expert testimony, the question whether the advertising is true or false will likely go to the jury, with the jury's verdict reviewable only deferentially. *See, e.g.*, *Pizza Hut, Inc. v. Papa John's Int'l, Inc.*, 227 F.3d 489, 500 & n.10 (5th Cir. 2000) (sustaining jury verdict based on expert evidence). And a Lanham Act judgment may even result in an injunction against the use of the false advertising—in other words, a jury may bar what the FDA has expressly authorized. Where the allegedly false statement pertains to compliance with the FDCA, its requirements, and the requirements thereunder, the Lanham Act suit amounts to enforcement of the FDCA.

Bioequivalence is a useful example of an FDA determination that cannot properly be litigated in a Lanham Act case. The FDA cannot approve a generic drug unless it is "bioequivalent" to another drug that has already gone through the FDA's approval process for new drugs, and its active ingredient or ingredients are the same as those of the brand-name drug. *See* 21 U.S.C. § 355(j)(2)(A)(iv), (j)(4)(C); *see also, e.g., Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1676 (2012). The FDA has considerable "discretion to determine what tests or studies would provide it with appropriate information from which to determine" bioequivalence or the identity of active ingredients, *Schering Corp. v. FDA*, 51 F.3d 390, 399-400 (3d Cir. 1995); *Serono Labs., Inc. v. Shalala*, 158 F.3d 1313, 1319 (D.C. Cir. 1998). That is because "the statute does not restrict applicants to a specific method for demonstrating bioequivalence." 57 Fed. Reg. 17,950, 17,977 (Apr. 28, 1992). Indeed, the statute expressly allows the FDA to decide on a drug-by-drug basis whether bioequivalence must be established through "in vitro" bioequivalence studies (laboratory testing), "in vivo" studies (testing on human subjects), "or both such studies." 21 U.S.C. § 355(j)(7)(A)(i)(III). The FDA has promulgated detailed regulations on that subject as well. See, *e.g.*, 21 C.F.R. §§ 320.21(b), (f), 320.22. Ultimately, the FDA has discretion to adopt "[a]ny . . . approach" that it "deem[s] adequate" to "establish bioequivalence," *id.* § 320.24(b)(6), and "[t]he preferred method . . . is determined on a case-by-case basis, depending on the drug under study." 57 Fed. Reg. at 17,972.

Once the FDA determines that a proposed generic drug is bioequivalent to an approved drug and meets

the other criteria necessary for approval, competitors and others with standing are free to challenge that conclusion. *See, e.g.*, *Serono*, 158 F.3d at 1318-19 (discussing challenge to FDA's conclusion that active ingredients were the same). That challenge proceeds under the familiar standard of the APA: it is brought against the agency or its head, not the generic drug maker; money damages are not available; review is limited to the administrative record; and the reviewing court grants a "high level of deference" to the FDA's interpretation of "scientific data within its area of expertise." *Id.* at 1320 (citation omitted).

A competitor would have no reason to proceed through that administrative challenge, however, if it could achieve the same result (or better) by suing under the Lanham Act. Alleging that the generic product was falsely marketed as "bioequivalent" to another drug, or as containing the same active ingredient, would allow the plaintiff to seek a jury trial and potentially win not just an injunction, but a substantial sum of money damages. But the import of such a lawsuit is that the FDA has allowed a drug onto the market that does not meet the FDCA's criteria for approval, even where the FDA has made an explicit determination that the drug does meet those criteria and the jury is being asked to disagree. That is an impermissible attempt to enforce the FDCA privately, and it is barred by Section 337(a) on the reasoning discussed above. *See, e.g.*, *Wyeth*, 2010 WL 746394, at *4.

If accepting a plaintiff's Lanham Act theory of falsity would compel the conclusion that the product violates the FDCA, *e.g.*, because it should not have

been approved or its labeling is false or misleading, then the Lanham Act claim is barred.

C. Considerations of Agency Deference and Fair Notice Preclude Punishing a Defendant Who Relies on the FDA

In this highly regulated area, the FDA often "does not give . . . words their ordinary English meanings." *United States v. 50 Boxes More or Less*, 909 F.2d 24, 25-26 (1st Cir. 1990) (Breyer, C.J.). And indeed, regulated parties need to comply with FDA's administratively-defined meanings rather than with terms' plain meaning. *See, e.g.*, 21 C.F.R. § 101.60(b)(1) ("zero calories" describes food with less than 5 calories in a specified portion).

Substituting a private civil action under the Lanham Act creates the risk that two rival meanings of the relevant legal terms will emerge: the meaning that FDA uses, and on which it is entitled to deference, and the ordinary-English meaning of those terms, on which a Lanham Act jury will premise liability. That result runs directly against two bedrock rules: that an agency deserves primacy in interpreting its own regulations, and that the government will not direct regulated parties to do one thing and then punish it for not doing something else.

That principle is particularly important where Congress has given the FDA authority not only to answer a certain scientific question, but also to specify *how* it is to be answered. For instance, in deciding whether a generic drug is "bioequivalent" to a brand-name drug, the FDA is authorized to decide what kind of scientific studies to require (laboratory testing versus testing in human subjects) and what con-

stitutes a "significant" difference in bioavailability. 21 U.S.C. § 355(j)(7)(A)(i)(III), (j)(8)(B)-(C). Allowing Lanham Act plaintiffs to use their own standards, their own science, and their own scientists to prove the falsity of a claim of bioequivalence would upset that delegation. Recognizing the need for clear and predictable rules, Congress directed the FDA to write them—fully intending that the regulated community would rely on them. *See, e.g., id.* § 355(j)(3)(C) (recognizing reliance interest in study design). Allowing a Lanham Act plaintiff to come along later and convince a jury to adopt *his* experts' hindsight approach is altogether incompatible with that congressionally-conferred reliance interest. Petitioner does not meaningfully disagree. *See, e.g.*, Pet'r Br. 38 (acknowledging that a different rule could apply if the "agency . . . sought to encourage the conduct being challenged").

II. In Deciding This Case, This Court Should Be Cognizant of the Differences Within the FDCA

This Court should decide this case with careful attention to the varying procedures that the FDA applies to food, drugs, and devices, and to the corresponding differences in the provisions of the FDCA. Petitioner's briefing suggests a willingness to obscure those important differences.

Petitioner brought this case here asserting a conflict in the courts of appeals over the intersection between the Lanham Act and the FDCA (as well as other statutes such as the pesticide-regulation statute). The government correctly explained that this case was a rarity because it involved the FDCA pro-

visions governing food, whereas most of the cases in the courts of appeals involved other regulated areas. U.S. Cert.-Stage Amicus Br. 19-20. Petitioner, however, insisted that the Court should take up this "one . . . case" to "provid[e] the lower courts with guidance" as to all the "distinct FDA regulatory schemes." Pet'r Cert.-Stage Supp. Br. 10. Indeed, petitioner perceived the rule advocated by the government to "ha[ve] nothing to do with whether the subject matter of the agency's regulation is 'food' or something else." *Id.*

Petitioner now focuses more of its arguments on aspects specific to food-label regulation. *See, e.g.*, Pet'r Br. 28-31. But petitioner has not abandoned its broader arguments, which risk conflating aspects of the FDCA that are quite different both substantively and procedurally. While there are numerous differences between food-label regulation and, *e.g.*, drug regulation, a few points are particularly salient here.

A. The FDA Does Not Review Juice Labels Individually, But Does Conduct Individual Review in Other Contexts

This case involves a categorical determination by the agency that juice mixtures may use a common name like the one respondent has given its "Pomegranate Blueberry Flavored" drink. The agency has chosen to do that by regulation because it "does not approve juice labels" individually. U.S. Cert.-Stage Amicus Br. 16. At a minimum, that regulation sets forth the agency's view that a juice mixture like respondent's is not "false" or "misleading," and therefore is not "misbranded," merely by virtue of its common name. 21 U.S.C. § 343(a)(1).

Petitioner contends (and the government agrees in part) that the *rest* of the label is fair game for a Lanham Act lawsuit. They state that because there is no regulation governing the aspects of the label that respondent finds objectionable, and because there is no individual review of respondent's label by FDA, the Lanham Act remedy is not ousted.[4] Pet'r Supp. Br. 4-5; U.S. Cert.-Stage Amicus Br. 9-11, 15-16.

Whatever the merits of that argument, it does not apply in other contexts where the FDA *does*, in fact, conduct individualized review in the context of an approval. As noted, the government specifically states that "affirmative FDA *approval* of specific labeling—*as in the prescription drug context, for example*, see 21 U.S.C. 355(d)—would preclude a claim under Section 43(a) of the Lanham Act, if that claim rested on grounds that would conflict with a determination underlying the agency's approval." U.S. Cert.-Stage Amicus Br. 16 (second emphasis added). In that context, the agency is obliged to review each and every element of the statutory test for approval of a drug, including whether any element of the labeling is misleading, before it allows the drug to go on the market.[5] A Lanham Act claim premised on the notion that the agency missed something in its review is no different than a claim that the agency affirmatively erred. Both types of claim assert that the drug is on the market in violation of the FDCA, and both are barred by the principle that private parties may not enforce the FDCA.

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[4] Respondent disputes that there is no regulation on point.

[5] The requirements for premarket approval of medical devices are similar. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 318 (2008) (discussing 21 U.S.C. § 360e(d)(1)(A)).

Indeed, any rule that rewarded non-exhaustion would discourage objectors from bringing concerns to the FDA and encourage them to go to court instead. That would be exactly the wrong outcome, considering that the agency possesses both the scientific expertise to evaluate any such concern and the primary role in protecting the public health and safety from misbranded food, drugs, and devices.

B. The FDA Reviews Drug Advertising

The FDA is charged with ensuring that advertising for prescription drugs is not false or misleading. *See* 21 U.S.C. § 352(n). While in other areas regulated by the FDCA the Federal Trade Commission takes the lead in regulating advertising, the FDA "has primary responsibility with respect to the regulation of the truth or falsity of prescription drug advertising." Memorandum of Understanding Between FTC and FDA, MOU 225-71-8003 (1971). The FDA has therefore promulgated regulations prohibiting specific deceptive practices in prescription drug advertising. 21 C.F.R. § 202.1(e)(5)-(7).

In carrying out its function, the FDA is sometimes, in exceptional cases (*see* 21 U.S.C. § 352(n)(3)(A)), called upon to review particular advertisements before they run. For example, the FDA has specified certain categories of advertising that it deems generally impermissible, but the FDA may approve particular prescription drug advertising within those categories based on a showing that an advertisement is "not false, lacking in fair balance, or otherwise misleading." 21 C.F.R. § 202.1(e)(6) (proviso). The FDA may also review advertisements submitted voluntarily.

At a minimum, the FDA's approval of an individual advertisement must be enough to give the regulated entity confidence that the advertisement is not false or misleading. For a private plaintiff to come along and second-guess the FDA's guidance would render that guidance altogether meaningless. That is not what the designers intended.

C. The Savings Clause on Which Petitioner And the Government Rely Is Limited To Food Labeling

While no state-law claim is at issue here, both petitioner and the government seek to draw inferential support from a clause saving state-law claims from preemption—but *only* in the food context. U.S. Cert.-Stage Amicus Br. 10, 11; Pet. 17-18. The preemption provisions of the Nutrition Labeling and Education Act of 1990, 21 U.S.C. § 343-1(a) & note, apply only to food labeling. Its exception from preemption for state-law food-labeling requirements that are "identical to" federal law has no bearing on any other portion of the FDCA. [6]

In the generic-drug context in particular, the preemption rule is considerably different. *See, e.g.*, *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011); *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013). At a minimum, there is no statutory blessing for addi-

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[6] Indeed, it is doubtful that the savings clause even supports the inference in the food context. The fact that Congress has saved some "identical" state-law claims from preemption, or has failed to preempt other state-law claims (Pet'r Br. 28-32), does not mean that Congress itself has *created*, in the Lanham Act, a separate but "identical" federal cause of action that plaintiffs may pursue despite the bar on private enforcement of the FDCA.

tional, separately enforceable requirements to be placed on generic drug manufacturers. And where a state-law claim directly implicates the FDA's role, there is a strong case for *conflict* preemption, even if there is an exception to *express* preemption. *See Buckman*, 531 U.S. at 352-53 (discussing Section 337(a) and explaining why state causes of action dependent on the FDCA are conflict-preempted even if they are within a statutory savings clause).

In particular, the savings clause for food labeling requirements "identical to" the federal requirements cannot provide any support for a Lanham Act claim based on *disagreement* with how the FDA has applied the federal requirements. When the FDA applies a statutory term like "bioequivalent," it is interpreting federal law, and its interpretation is entitled to deference. A jury's decision to disagree with such a determination is hardly the application of an "identical" standard.

At least outside the food-related context at issue here, there can be no inference that Congress specifically intended private enforcement through the Lanham Act. That aspect of petitioner's reasoning therefore is limited to the context of this case, not to the entire FDCA.

CONCLUSION

The judgment of the court of appeals should be affirmed. In the alternative, the terms of any reversal and remand should be limited to the context in which the FDA has not reviewed a food label and has not specifically dealt with the allegedly misleading content or design in a regulation.

Respectfully submitted.

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March 3, 2014

AMICUS CURIAE BRIEF

RECORD AND BRIEFS

No. 12-761

Supreme Court, U.S.
FILED
MAR - 3 2014
OFFICE OF THE CLERK

IN THE

Supreme Court of the United States

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BRIEF FOR AMICUS CURIAE INTERNATIONAL TRADEMARK ASSOCIATION IN SUPPORT OF PETITIONER

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BRIEF FOR AMICUS CURIAE INTERNATIONAL TRADEMARK ASSOCIATION IN SUPPORT OF PETITIONER

INTEREST OF AMICUS CURIAE[1]

Founded in 1878, the International Trademark Association ("INTA") is a global organization dedicated to supporting trademarks and related

[1] In accordance with Supreme Court Rule 37.6, amicus curiae states that this brief was authored solely by INTA and its counsel, and no part of this brief was authored by counsel to a party. No party or counsel for a party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than amicus curiae, its members, and its counsel made such a monetary contribution to its preparation or submission. The parties have consented to the filing of this brief, and letters indicating the consent are filed with this brief.

intellectual property in order to protect consumers and to promote fair and effective commerce. INTA has more than 6,400 members in more than 190 countries. Its members include trademark and brand owners, as well as law firms and other professionals who regularly assist brand owners in the creation, registration, protection, and enforcement of their trademarks. All INTA members share the goal of promoting an understanding of the essential role that trademarks and goodwill play in fostering commerce, fair competition, and informed decision-making by consumers.

INTA was founded in part to encourage the enactment of federal trademark legislation after invalidation on constitutional grounds of the United States' first trademark act. Since then, INTA has been instrumental in making recommendations and providing assistance to legislators in connection with major trademark and related legislation. INTA members are frequent participants in Lanham Act–related litigation as both plaintiffs and defendants. INTA has also participated as amicus curiae in numerous cases involving significant Lanham Act issues in this Court and others.[2]

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[2] INTA has filed amicus briefs in this Court in the following matters: *Lexmark Int'l* v. *Static Control Components*, No. 12-873 (Sup. Ct., pet. granted June 3, 2013); *Already, LLC* v. *Nike, Inc.*, 133 S. Ct. 721 (2013); *KP Permanent Make-Up, Inc.* v. *Lasting Impression I, Inc.*, 543 U.S. 111 (2004); *Dastar Corp.* v. *Twentieth Century Fox Film Corp.*, 539 U.S. 23 (2003); *Moseley* v. *V Secret Catalogue, Inc.*, 537 U.S. 418 (2003); *TrafFix Devices, Inc.* v. *Mktg. Displays, Inc.*, 532 U.S. 23 (2001); *Wal-Mart Stores, Inc.* v. *Samara Bros.*, 529 U.S. 205 (2000); *Fla. Prepaid Postsecondary Educ. Expense Bd.* v. *Coll. Sav. Bank*, 527 U.S. 627 (1999); *Qualitex Co.* v. *Jacobson Prods. Co.*, 514 U.S. 159 (1995); *Two Pesos, Inc.* v. *Taco Cabana, Inc.*, 505 U.S.

INTA and its members have a particular interest in this case because the Ninth Circuit's decision risks undermining the protection of consumers and promotion of fair and effective commerce that INTA's members value, and risks undermining the goal of informed decision-making by consumers. INTA (then known as the United States Trademark Association, or "USTA") was instrumental in the comprehensive revisions to the Lanham Act in 1988, including revisions to Section 43(a).[3] INTA takes no position with respect to the plausibility of the petitioner's allegations or the merits of its substantive claims. However, INTA is deeply concerned that the Ninth Circuit's ruling, which bars Section 43(a) suits when a product's naming and labeling are regulated under the Federal Food Drug & Cosmetic Act ("FDCA") and by the Food and Drug Administration ("FDA"), will eliminate the ability of businesses to promote fair competition and protect against consumer confusion by combatting false and misleading advertising. This is not what Congress intended and it is at odds with the interests of businesses, including many of INTA's members.

SUMMARY OF THE ARGUMENT

The Ninth Circuit's decision needlessly, and erroneously, eliminates an important, Congressionally-authorized tool that promotes fair

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763 (1992); and *K Mart Corp.* v. *Cartier, Inc.*, 486 U.S. 281 (1988).

[3] The USTA's 1987 Trademark Review Commission was a precursor to the Trademark Law Revision Act of 1988. *See* USTA, *Trademark Review Commission Report and Recommendations to USTA President and Board of Directors, reprinted in* The Trademark Law Revision Act of 1988 (1989) ("Commission Report").

competition through challenges to false and misleading advertising. The court of appeals' holding that the claim of Pom Wonderful ("Pom") under Section 43(a) of the Lanham Act was barred by the FDCA's juice labeling scheme disregards this Court's well-established rule that courts must give full effect to allegedly competing federal statutes unless they are in "irreconcilable conflict." *Branch* v. *Smith*, 538 U.S. 254, 273 (2003).

The Lanham Act and the FDCA can and do coexist without conflict. Congress intended Section 43(a) to give businesses a right to challenge false and misleading advertising through private actions. By contrast, the FDCA and the FDA's regulation of "misbranded" food is not intended to be—and has never been—an effective substitute for Lanham Act suits. If the FDA's regulatory authority is permitted to trump the Lanham Act, then U.S. businesses will be left without a federal remedy for false advertising of many types, contrary to Congress's intent, and at odds with the interests of businesses and consumers.

Not only is there no inherent conflict, the Lanham Act and FDCA actually work in tandem to ensure accurate and fair promotion of food, drugs and cosmetics. While FDA regulation plays an essential regulatory role, private business competitors are in the best position to understand the perpetual threats of false and misleading advertisements as they arise, and to contest them through Lanham Act suits. Businesses are better suited than the federal government to expend the resources needed to challenge specific instances of false and misleading advertising. By contrast, the FDA and other federal agencies will never be able to devote the same resources to combat particular advertisements, or

provide the remedies that the Lanham Act authorizes. The FDA is well-suited to promulgate and enforce minimum standards that promote the accuracy and clarity of food, drug and cosmetic labeling, but not to investigate whether a specific label that meets those standards nonetheless misleads or confuses consumers.

Section 43(a) harnesses the interests of competitors to enable them to act as the avengers of the public interest by reducing consumer confusion and ensuring accurate and fair advertising. The Ninth Circuit eliminates this benefit to the public, relying on federal agencies to police false and misleading advertising through the slow channels of regulation and enforcement. Because the FDA has not vigorously pursued misleading food labels, the Ninth Circuit's ruling would, in practice, leave beverage labeling largely un-policed. Moreover, the decision's sweeping reasoning could extend to other food and drug items, and to other federal agencies. By reversing the Ninth Circuit's decision, the Court recognizes Congress's intent to enact a broad, federal unfair competition law that promotes fair business competition and benefits the public interest.

ARGUMENT

I. THE NINTH CIRCUIT'S DECISION ERRONEOUSLY ELIMINATES AN IMPORTANT TOOL FOR COMBATTING FALSE OR MISLEADING ADVERTISING AND PROMOTING A FAIR MARKETPLACE.

The decision below gives broad preclusive effect to the FDCA's juice labeling scheme over claims for false and misleading advertising under Section 43(a)

of the Lanham Act. That holding and its sweeping reasoning should not stand. Congress endowed the Lanham Act and the FDCA (and the FDA's implementing regulations) with different purposes. As applied here, the statutes have no conflict—much less an "irreconcilable" conflict. To the contrary, Section 43(a) and the FDCA complement one another, and work in tandem to promote fair commerce and protect the public. This Court, unlike the court of appeals, should give both statutes full effect.

A. The Lanham Act And The FDCA Have Different Purposes.

In enacting the Trademark (Lanham) Act of 1946, Ch. 540, 60 Stat. 427, as amended, Congress intended to "regulate commerce * * * by making actionable the deceptive and misleading use of marks in such commerce * * *" and "protect persons engaged in such commerce against unfair competition." 15 U.S.C. § 1127.[4] Since its enactment in 1946, courts have widely interpreted Section 43(a) of the Lanham Act "as creating, in essence, a federal law of unfair competition." S. Rep. No. 515, 100th Cong., 2nd Sess. 1988 (Sept. 15, 1988), *reprinted in* 1988 U.S.C.C.A.N. 5577, 5603, 1988 WL 170248. By the 1970s, the courts' broad interpretations of Section 43(a) had transformed the provision into "a potent, far-reaching, commercial Bill of Rights for

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[4] Congressman Fritz Lanham, the bill's sponsor, stated that "[t]he purpose of [the Act] is to protect legitimate business and the consumers of the country." 92 Cong. Rec. 7524 (1946). *See also Two Pesos, Inc.*, 505 U.S. at 782 n.15 (Stevens, J., concurring) (noting Congress's intent to advance the dual goals of fostering fair competition and protecting the public from deceit).

the honest businessman," that reached "almost towering stature as a weapon to combat * * * unfair competition." *See* Commission Report, *supra*, at 378.

In 1988, with INTA's active support, Congress amended Section 43(a) "to codify the interpretation it has been given by the courts." S. Rep. No. 515, 100th Cong., 2nd Sess. 1988, *supra*; *see also Two Pesos, Inc.*, 505 U.S. at 783 ("[I]n the Trademark Law Revision Act of 1988 * * * Congress codified the judicial interpretation of § 43(a), giving its *imprimatur* to a growing body of case law from the Circuits that had expanded the section beyond its original language.").

As amended, Section 43(a) of the Lanham Act creates a private civil action against "[a]ny person who, on or in connection with * * * any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof * * * which * * * misrepresents the nature, characteristics, (or) qualities * * * of his * * * goods." 15 U.S.C. § 1125(a)(1). An action may be brought "by any person who believes that he or she is likely to be damaged by such an act." *Id.* The Lanham Act authorizes injunctive relief, as well as damages and disgorgement of a defendant's profits. 15 U.S.C. § 1117(a).

The Lanham Act is designed to "protect persons engaged in * * * commerce against unfair competition.'" *Dastar Corp.*, 539 U.S. at 28 (quoting 15 U.S.C. § 1127). Among its "salutary purposes" is "to promote fair competition in the marketplace," *Zenith Elecs. Corp.* v. *Exzec, Inc.*, 182 F.3d 1340, 1354 (Fed. Cir. 1999), and "to promote fair business dealing." *Parkway Baking Co.* v. *Freihofer Baking Co.*, 255 F.2d 641, 649 (3d Cir. 1958); *AT & T* v.

Winback and Conserve Program, Inc., 42 F.3d 1421, 1433-34 (3d Cir. 1994) ("The Lanham Act has the broad purpose of protecting competitors from a wide variety of misrepresentations of products and service[s]"); *Allsup, Inc.* v. *Advantage 2000 Consultants, Inc.*, 428 F.3d 1135, 1138 (8th Cir. 2005) (purpose of the Act is "to protect persons engaged in commerce against false advertising and unfair competition"). In particular, the purpose of Section 43(a)'s false advertising provisions "is to protect sellers from having their customers lured away from them by deceptive ads." *Schering-Plough Healthcare Prods.* v. *Schwarz Pharma, Inc.*, 586 F.3d 500, 512 (7th Cir. 2009).

By contrast, the FDCA has the "overriding purpose to protect the public health." *United States* v. *Bacto-Unidisk*, 394 U.S. 784, 798 (1969). The FDCA "safeguard[s] the consumer by applying the [FDCA] to articles from the moment of their introduction into interstate commerce all the way to the moment of their delivery to the ultimate consumer." *United States* v. *Sullivan*, 332 U.S. 689, 696 (1948); *see also United States* v. *Articles of Drug Consisting of Following: 5,906 Boxes*, 745 F.2d 105, 113 (1st Cir. 1984) (describing FDCA as a "comprehensive regulatory statute concerned with public safety").

Congress first regulated food and beverage labeling in the Federal Food and Drugs Act of 1906, Ch. 3915, 34 Stat. 768. It later enacted the FDCA, Ch. 675, 522 Stat. 1040, 21 U.S.C. § 301 *et seq.*, and has amended the act numerous times. Relevant here, in 1990 Congress amended the FDCA to address nutrition labeling for nearly all food products for human consumption, including juices. Nutrition

Labeling and Education Act of 1990 ("NLEA"), Pub. L. No. 101-535, 104 Stat. 2353.

While Section 43(a) of the Lanham Act bans false and misleading advertising, the FDCA bans the introduction into or receipt in commerce of "misbranded" foods. 21 U.S.C. § 331(a), (c). "Food" includes any "article [ ] used for * * * drink." 21 U.S.C. § 321(f). In regulating food and beverage labeling, the FDCA provides that food is "deemed to be misbranded" in several ways. 21 U.S.C. § 343. Food is misbranded if "its labeling is false or misleading in any particular," if required information is not sufficiently prominent and conspicuous on the labeling, or if its label fails to bear "the common or usual name of the food, if any there be, and * * * in case it is fabricated from two or more ingredients, the common or usual name of each ingredient." 21 U.S.C. § 343(a), (f), (i). The FDA has implemented numerous regulations of the naming and labeling of juices "to promote honesty and fair dealing in the interest of consumers." 21 U.S.C. § 341. *See* 58 Fed. Reg. 2898-2926 (Jan. 6, 1993); *see generally* 21 C.F.R. pts. 101, 102. The particular provision at issue in this case addresses the naming and labeling of multi-juice beverages. 21 C.F.R. § 102.33.

The FDCA and FDA regulations address the "misbranding" of juice labels, which has an obvious overlap with the false and misleading advertising forbidden by Section 43(a). Importantly, however, the FDCA and FDA regulations do not allow a private party to sue to remedy harms from misbranding. *See* 21 U.S.C. § 337(a) ("[A]ll such proceedings for the enforcement, or to restrain violations [of the FDCA] shall be by and in the name

of the United States."); *cf. Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001) ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance."). By contrast, a Lanham Act plaintiff who establishes that a defendant has falsely advertised or promoted its food product may be entitled to recover, in addition to broad injunctive relief, monetary relief in the form of damages and the disgorgement of the defendant's profits. 15 U.S.C. § 1117(a).

The FDCA permits a competitor to petition the FDA to undertake rulemaking to revise its labeling regulations for juice mixtures, 21 U.S.C. § 371(e)(1)(b), but such a rule would not redress the injuries to a Lanham Act plaintiff's business interests. A citizen's petition could only be used to ask the FDA to "[p]ublish a proposal to issue, amend, or revoke * * * a regulation," 21 C.F.R. § 102.19(a), not to stop a particular instance of false advertising. At best, the result of the petition might be a sledgehammer when a laser is called for. *See also* U.S. Amicus Br. 15. While the FDA can seek to enjoin a defendant promoting its food product with a label that is false or misleading, the agency does not have authority to seek civil monetary penalties for such conduct.[5] Nor can the FDA compensate a

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[5] Congress has authorized the FDA to seek civil monetary penalties for violations of certain specific provisions of the FDCA, but has chosen not to do so with respect to food labeling provisions. *See, e.g.*, 21 U.S.C. § 333(b)(2) (drug marketing violations); § 333(f)(9) (tobacco product violations); 21 C.F.R. § 17.1 (listing "the statutory provisions that authorize civil money penalties"); *but see* 21 U.S.C. § 343 (food labeling, with no provision for civil monetary penalties).

business for lost sales or goodwill resulting from false food advertising or for the costs a business incurs responding to false advertising. "An injunction can halt a wrongful activity but it will not correct its effects." *Balance Dynamics Corp.* v. *Schmitt Indus.*, 204 F.3d 683, 698 (6th Cir. 2000).

Thus, Section 43(a) of the Lanham Act and the FDCA's and FDA's "misbranding" scheme serve different purposes. The Lanham Act promotes a fair marketplace, and protects businesses by enabling them to sue for false and misleading advertising to stop and redress those harms. The FDCA is a public safety statute, concerned with ensuring that food, drugs and cosmetics are safe and that their labels do not misrepresent the nature of the products; it is not concerned with whether false and misleading advertising harms the manufacturer's or producers' business interests. Rather than providing private remedies, Congress reserved enforcement for the FDA, leaving private parties to petition the FDA and seek broad regulatory changes through the agency's rulemaking.

Courts have also recognized the divergence of purposes between the Lanham Act and the FDCA's drug labeling provisions. The FDCA "'is not focused on the truth or falsity of advertising claims,' but is * * * directed to protecting the public by ensuring that drugs sold in the marketplace are 'safe, effective and not misbranded,' a task vested in the FDA to implement and enforce." *Mut. Pharm.* v. *Ivax Pharm., Inc.*, 459 F. Supp. 2d 925, 933 (C.D. Cal. 2006) (quoting *Sandoz Pharm.* v. *Richardson-Vicks, Inc.*, 902 F.2d 222, 230 (3d Cir. 1990)). "[T]he main purpose of the advertising restrictions set forth in the FDCA and its accompanying regulations is not to

protect consumers from deceptive advertising, but rather to further the FDCA's underlying goal of ensuring the safety of prescription drugs." *In re Epogen & Aranesp Off-Label Mktg. & Sales Practices Litig.*, 590 F. Supp. 2d 1282, 1290 (C.D. Cal. 2008); *see also Iams Co.* v. *Nutro Prods., Inc.*, No. C–3–00–566, 2004 WL 5780000, at * 2 (S.D. Ohio July 19, 2004) (stating that FDCA "is not focused on the truth or falsity of advertising claims").

The statutes are capable of coexisting and Congress has never indicated that they should not coexist. Indeed, Congress created the Lanham Act's private right of action after authorizing the FDA to regulate the misbranding of food products. 21 U.S.C. §§ 331-334, 343, 371 (Supp. IV 1938); 15 U.S.C. § 1125 (1946). Congress has amended both laws on multiple occasions without attempting to eliminate any overlap between the statutes. Had Congress intended to eliminate Lanham Act suits related to misbranding, it knew how to do so. *Cf. Wyeth* v. *Levine*, 555 U.S. 555, 574 (2009) ("If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history."). As the United States argues, "nothing in the FDCA, the NLEA, FDA's regulations, or the preambles to those regulations suggests that FDA has marked the metes and bounds of all possible misleading material on juice labels, or that its authority must be deemed exclusive even as to matters the agency has never specifically addressed." U.S. Amicus Br. 12.

In sum, the Lanham Act and the FDCA serve different purposes. With respect to juice labeling, there is overlap where both statutes address naming

or labeling of products. A primary purpose of the Lanham Act is to protect private competitors by enabling them to challenge false or misleading advertising. The purpose of the FDCA and FDA regulations is to specify standards for labeling for the purpose of keeping the public safe, with compliance enforced by the FDA.

B. The Ninth Circuit's Decision Fails To Identify Any Irreconcilable Conflict Between Section 43(a) And The FDCA's Misbranding Scheme.

In reconciling potentially overlapping federal statutes, this Court requires courts to give full effect to allegedly competing federal statutes unless they are in "'irreconcilable conflict.'" *Branch*, 538 U.S. at 273 (quoting *Posadas* v. *Nat'l City Bank*, 296 U.S. 497, 503 (1936)). "[W]hen two statutes are capable of coexistence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective." *Morton* v. *Mancari*, 417 U.S. 535, 551 (1974). Courts are "not at liberty to pick and choose among congressional enactments." *Id.*; *United States* v. *Borden Co.*, 308 U.S. 188, 198 (1939) ("When there are two acts upon the same subject, the rule is to give effect to both if possible."). Statutes that "overlap" or may appear to be somewhat "redundan[t]" can be "fully capable of coexisting." *United States* v. *Batchelder*, 442 U.S. 114, 118, 122 (1979).

There is no "irreconcilable conflict" between Section 43(a) of the Lanham Act and the FDCA. *Branch*, 538 U.S. at 273. In fact, the court of appeals' opinion fails even to address whether the statutes meet this standard. Instead, the court of appeals gave effect to the FDCA, and not the Lanham Act, by precluding

the application of Section 43(a) to a broad range of potentially misleading statements solely on the ground that they are subject to FDA regulation. Pet. App. 8a ("[T]he Lanham Act may not be used as a vehicle to usurp, preempt, or undermine FDA authority."). The court of appeals concluded that "the FDCA and its regulations bar pursuit of both the name and labeling aspects of [Pom's] Lanham Act claim." Pet. App. 9a.

With respect to the name of the product at issue, the court explained that because 21 C.F.R. § 102.33(d) permits a manufacturer to name a beverage using the name of a flavoring juice that is not predominant, "as best we can tell, FDA regulations authorize the name [Coca-Cola] has chosen." Pet. App. 9a. According to the court of appeals, Pom's challenge to the common name "Pomegranate Blueberry Flavored Blend of 5 Juices" would create a conflict with FDA regulations and would "require [the court] to undermine the FDA's apparent determination that so naming the product is not misleading." *Id.*[6]

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[6] There are some recognized limits on a Lanham Act plaintiff's ability to sue in areas the FDA regulates. A plaintiff may not, for example, sue under the Lanham Act claiming that an advertisement is false or misleading because it violates the FDCA or its regulations — allowing such a suit could conflict with Congress's decision to limit enforcement of the FDCA to the federal government. *See, e.g., Mylan Labs., Inc.* v. *Matkari*, 7 F.3d 1130, 1149 (4th Cir. 1993). This is particularly true where a Lanham Act claim is based on an alleged violation of an FDCA provision and would require the court to preemptively interpret and apply ambiguous FDA regulations or to predict the FDA's future and discretionary decisions. *See, e.g., Sandoz*, 902 F.2d at 231-32 (claim that drug label falsely described ingredient as "inactive" was barred because the issue of whether the ingredient was active or inactive was under FDA

With respect to Coca-Cola's labeling of the product, the court of appeals concluded that Pom's Lanham Act claim was precluded with respect to the label's presentation of the words "Pomegranate Blueberry" in "larger, more conspicuous type" than the words "Flavored Blend of 5 Juices" appearing below them. Pet. App. 10a. The FDCA and its implementing regulations "have specified how prominently and conspicuously those words and statements must appear." *Id.* (citing 21 U.S.C. § 343(f), (i) and 21 C.F.R. § 102.33(c), (d)). "Congress and the FDA have thus considered and spoken to what content a label must bear, and the relevant sizes in which the label must bear it, so as not to deceive," but "ha[ve] not (so far as we can tell) required that all words in a juice blend's name appear on the label in the same size." *Id.* "[I]f the FDA believes more should be done to prevent deception, or that [Coca-Cola's] label misleads consumers, it can act." *Id.* at 11.

In the court of appeals' view, allowing Pom's Lanham Act challenge to Coca-Cola's label would "risk undercutting the FDA's expert judgments and authority." Pet. 9a-11a. The court did not want to contravene what it perceived to be "Congress's decision to entrust matters of juice beverage labeling to the FDA and * * * the FDA's comprehensive regulation of that labeling." *Id.* at 12a.

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review). However, a Lanham Act claim may proceed even when it "turns on the meaning of [FDA] publications in the Federal Register and Code of Federal Regulations." *See Alpharma Inc.* v. *Pennfield Oil Co.*, 411 F.3d 934, 939 (8th Cir. 2005) ("Interpretation of such materials is well within the conventional experience of judges") (internal quotation omitted). Because such claims do not depend upon proving an FDCA violation, they are "fully capable of coexisting" with that statute. *See Batchelder*, 442 U.S. at 118.

The court of appeals specifically emphasized that it was not "hold[ing] that [Coca-Cola's] label is non-deceptive," or that "mere compliance with the FDCA or with FDA regulations will always (or even generally) insulate a defendant from Lanham Act liability." Pet. App. 11a-12a.

But in light of the court's otherwise sweeping reasoning, the latter caveat is toothless. The court stated that it was guided by what it understood to be "Congress's decision to entrust matters of juice beverage labeling to the FDA and by the FDA's comprehensive regulation of that labeling." *Id.* at 12a. From the perspective of market participants such as INTA's members, that reasoning would "insulate a defendant from Lanham Act liability," Pet. App. 12a, in essentially every instance of juice labeling as well as labeling of most other products the FDA regulates. If the FDA's juice regulations at issue here—which the parties agree only permitted, but did not require, Coca-Cola's labeling—are "comprehensive regulation" of labeling, then there is a risk that nearly anytime the FDA regulates an aspect of a product with some degree of specificity, then FDA's regulation may be deemed "comprehensive" enough to preclude a Lanham Act suit.

The United States also argues that the court of appeals' "reasoning is too broad." *See* U.S. Amicus Br. 10-15. In the government's view, the court of appeals should have permitted Pom's Lanham Act challenge insofar as it concerns features of the juice's label that are not specifically addressed by the FDCA or the FDA's regulations. U.S. Amicus Br. 8. The Ninth Circuit's observation that the FDA had not, but could have, regulated the aspects of the label to

which Pom objected "endowed the FDCA's food labeling provisions with too broad a preclusive reach." *Id.* The mere existence of a federal regulatory or enforcement scheme does not create a conflict between federal statutes. To hold otherwise, the government correctly argues, would be "tantamount to saying that whenever a federal agency decides to step into a field, its regulations will be exclusive." U.S. Amicus Br. 11 (quoting *Hillsborough Cnty.* v. *Automated Med. Labs., Inc.*, 471 U.S. 707, 717 (1985)). The Ninth Circuit was too quick to regard the commitment of authority to the FDA as exclusive. *Id.*

Furthermore, the Ninth Circuit's reasoning conflicts with other circuit courts that have rejected similarly overbroad preclusion of Lanham Act claims. In *Cottrell, Ltd.* v. *Biotrol Int'l, Inc.*, 191 F.3d 1248 (10th Cir. 1999), the Tenth Circuit approved of the general view that "[a]ffirmative misrepresentations * * * are generally actionable under the Lanham Act, even if the product is regulated by the FDA," *id.* at 1254 (internal citation and quotation omitted), and recognized the difference between a Lanham Act plaintiff's impermissible "attempt[ ] to enforce" federal regulations and "vindicat[ing] its rights under the Lanham Act independent of the regulation." *Id.* at 1254. The court rejected the view (indistinguishable from the Ninth Circuit's) that a Lanham Act claim must be dismissed because it "touches on issues" covered by federal regulatory authority, *id.* at 1256, and refused to preclude the Lanham Act claim where (like here) the agency's authority "nowhere explicitly precludes Lanham Act coverage." *Id.* at 1256.

Similarly, the Third Circuit permitted a Lanham Act false advertising claim to proceed notwithstanding the FDA's authority to regulate the advertising at issue, *Sandoz*, 902 F.2d at 228-29, but barred a claim based on defendant's alleged violation of an FDCA provision that would have required the court to "determine preemptively" how the FDA would "interpret and enforce its own regulations," *id.* at 231. *See also Alpharma*, 411 F.3d at 940-41 (refusing to preclude Lanham Act claim that did not require a determination by the court of how the FDA would interpret and enforce its own regulations).

The court of appeals' overbroad interpretation of the FDCA's preclusive effect is erroneous, and should be reversed. Section 43(a) of the Lanham Act and the FDCA's "misbranding" regulations have no conflict, much less an "irreconcilable" conflict, and the statutes are "fully capable of coexisting," *Batchelder*, 442 U.S. at 118, 122; *Silver* v. *N.Y. Stock Exch.*, 373 U.S. 341, 357 (1963) ("the proper approach to this case, in our view, is an analysis which reconciles the operation of both statutory schemes with one another rather than holding one completely ousted"). More than that, they harmoniously work together to enable businesses to promote a fair marketplace, and protect consumers from confusion about products.

C. The Lanham Act And The FDCA Work In Tandem.

Private Lanham Act suits should not be banished from the domain of food and beverage labeling, and, to the contrary, should be allowed to work in tandem with the FDCA to promote the purposes Congress intended them to serve.

In this case, the dispute is whether the name and labeling of the "Pomegranate Blueberry" product are misleading to consumers. Under the Ninth Circuit's ruling, Pom is precluded from using its resources to survey consumers to build a Lanham Act Section 43(a) case that challenges its competitor's product's name and labeling as misleading based on actual evidence of deception.[7] Pom is also precluded from seeking damages or other relief for any harm caused. Instead, Pom is left to await a time when "the FDA believes that more should be done to prevent deception," and "act[s]." Pet. App. 11a. The court of appeals concluded that "[i]n the circumstances here, the appropriate forum for [Pom's] complaints is the FDA." *Id.* (quoting *PhotoMedex, Inc.* v. *Irwin*, 601 F.3d 919, 929 (9th Cir. 2010)).

By limiting the ability of private parties to challenge false and misleading advertising only through a petition to the FDA, the Ninth Circuit eliminates—for all practical purposes—the Lanham Act as a tool for private parties to fight such advertising's effects. The slow wheels of federal rulemaking and the floor they set can never keep pace with the threats false advertising pose to a fair marketplace, and the necessarily broad scope of regulation cannot evaluate an actual likelihood of deception or confusion in specific instances of false advertising. Products are introduced or relabeled all the time. Disputes over labels, such as the juice label in this case, flare up quickly, and the harms from unfair competition quickly take their toll on market participants and consumers. The entities

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[7] As noted, INTA takes no position on the substantive merits of Pom's claim, which were not reached by the Ninth Circuit.

best positioned to understand and investigate instances of false advertising are the businesses whose interests are injured, even though the labeling at issue will often concern an area important enough for the FDA to have issued broad, relevant regulations. *See Coca-Cola Co.* v. *Procter & Gamble Co.*, 822 F.2d 28, 31 (6th Cir. 1987) ("Under our economic system, competitors have the greatest interest in stopping misleading advertising, and a private cause of action under section 43(a) allows those parties with the greatest interest in enforcement and in many situations with the greatest resources to devote to a lawsuit, to enforce the statute rigorously").

Indeed, this case well illustrates how a business can use a Lanham Act claim to address relatively quickly a specific instance of potentially misleading advertising. As a party typically does in preparing a Lanham Act suit, Pom commissioned a marketing and public opinion research firm to conduct a field survey to test whether consumer confusion about the product exists. Pet. App. 32. *Hickson Corp.* v. *N. Crossarm Co., Inc.*, 357 F.3d 1256, 1261 (11th Cir. 2004) ("Consumer survey research often is a key part of a Lanham Act claim alleging that an advertisement is misleading or deceptive."); *Johnson & Johnson Merck Consumer Pharms. Co.* v. *Smithkline Beecham Corp.*, 960 F.2d 294, 298 (2d Cir. 1992) ("[T]he success of a plaintiff's implied falsity claim usually turns on the persuasiveness of a consumer survey."). Pom contends that the survey demonstrates that "a substantial proportion of potential purchasers of pomegranate and blueberry juice blends are likely to mistakenly believe" Coca-Cola's juice consists mainly of pomegranate and

blueberry juice, rather than other cheaper juices. Pet. App. 33a.

When Lanham Act suits are not barred (as the Ninth Circuit has done), a business can take such evidence to trial and resolve the dispute. If it prevails, it can obtain injunctive relief, damages and remedies such as disgorgement that can resolve the dispute. Or if the claim cannot be proven, the dispute may go away. The private parties who have the most direct interest in the dispute bear the brunt of the costs of the litigation. The federal government cannot hope to devote similar resources and sustained focus on particular advertisements. In effect, the Lanham Act harnesses a market-type mechanism to enable businesses to act on their own interests to police false and misleading advertising. And the threat of such litigation can help promote a fair marketplace because businesses know they risk a Lanham Act suit if they promote products with false and misleading labels.

Allowing the Lanham Act to harness the interests of businesses in this manner to police false and misleading advertising does not mean the FDCA and FDA regulations have no role to play. They have a unique and indispensable regulatory role. For example, 21 C.F.R. § 102.33(d) permits a manufacturer to name a beverage using the name of a flavoring juice that is not predominant. It may be that "FDA regulations authorize the name [Coca-Cola] has chosen." Pet. App. 9a. The FDA has considered naming and issued a broad regulation, and Coca-Cola has apparently complied with it, but that alone does not require the conclusion that Pom could never prove through surveys and other evidence that the specific name is not misleading.

And the FDCA does not address whether Pom has suffered commercial harm from the misleading name, and how the harm can be redressed.

Similarly, the court of appeals concluded that Pom's Lanham Act claim was precluded with respect to the label's presentation of the words "Pomegranate Blueberry" in "larger, more conspicuous type" than the words "Flavored Blend of 5 Juices" appearing below them. Pet. App. 10a. It may be that the FDCA and its implementing regulations "have specified how prominently and conspicuously those words and statements must appear." *Id.* (citing 21 U.S.C. § 343(f), (i) and 21 C.F.R. § 102.33(c), (d)). And this might reflect the fact that "Congress and the FDA have thus considered and spoken to what content a label must bear, and the relevant sizes in which the label must bear it, so as not to deceive," but not "required that all words in a juice blend's name appear on the label in the same size." *Id.* But it does not follow that Pom must wait until the FDA "believes more should be done to prevent perceived * * * deception," and decides to "act." *Id.* at 11. The FDCA contains provisions regarding the prominence of information on food labels (*e.g.*, 21 U.S.C. § 343(f)), and there is no dispute that the product at issue complies, or is not inconsistent, with them. But this is a different inquiry than whether the accused product name and labeling are in fact likely to mislead the consumer. A plaintiff should be permitted to take its claims and its proof of consumer deception to trial, and if it establishes its case, it should be entitled to redress under the Lanham Act. In that way, Congress's purposes under both the Lanham Act and the FDCA

are given full effect, as the Court must do. *Branch*, 538 U.S. at 273.

Allowing private parties to pursue remedies under Section 43(a) does not result in a corresponding reduction in the public safety that the FDCA is designed to protect. In this case, Pom argues that Coca-Cola could have complied with both the Lanham Act's and the FDA's requirements. Pet. 14. Indeed, there are also benefits to consumer safety that result from the Lanham Act. *Schering-Plough*, 586 F.3d at 512 ("[I]f no one is or could be fooled, no one is or could be hurt."). Whenever a Lanham Act plaintiff is vindicated in litigation, consumers benefit because the false or misleading advertising has been made known to the public and in most instances is corrected. Also, the potential risk of being sued under the Lanham Act discourages businesses from using false or misleading advertising to market their products.

II. PREVENTING PRIVATE LANHAM ACT SUITS WOULD HAVE FAR-REACHING IMPLICATIONS FOR THE PROTECTION OF CONSUMERS.

For decades, INTA has vigorously advocated in support of the Lanham Act not only because it promotes the commercial interests of its member businesses, but also because the law benefits the informed decision-making of the consumers who buy their products. If the Ninth Circuit's decision is allowed to stand, it would significantly diminish the statute's protection of consumers.

It was once the view that "the law does not allow [the federal false advertising plaintiff] to sue as a vicarious avenger of the defendant's customers." *Ely-*

Norris Safe Co. v. *Mosler Safe Co.*, 7 F.2d 603, 604 (2d Cir. 1925) (Hand, L., J.), *rev'd on other grounds by Mosler Safe Co.* v. *Ely-Norris Safe Co.*, 273 U.S. 132 (1927). Today, Section 43(a)'s false advertising prohibitions are understood to "allow[ ] a commercial plaintiff to act as a vicarious avenger of the consumer interest in not being deceived by false advertising." 5 McCarthy on Trademarks and Unfair Competition § 27:2 (4th ed. 2009).

"While unarticulated in the Act itself," Section 43(a)'s purpose includes the "protection of the consuming public from false representations and descriptions in connection with the advertising of goods and services." *Ames Pub. Co.* v. *Walker-Davis Publ'ns, Inc.*, 372 F. Supp. 1, 13-14 (E.D. Pa. 1974); *U-Haul Int'l, Inc.* v. *Jartran, Inc.*, 681 F.2d 1159, 1162 (9th Cir. 1982) (noting that the Lanham Act is directed toward protecting the consumer as well as business from false and deceptive advertising, and observing that Congress intended "'to protect the public from imposition by the use of * * * false trade descriptions.'") (internal citation omitted). The policy behind the Lanham Act is "to balance the protection of consumers from confusion, against the desired free competition within the market place." *Goddard, Inc.* v. *Henry's Foods, Inc.*, 291 F. Supp. 2d 1021, 1049 (D. Minn. 2003), *see also Coca-Cola Co.*, 822 F.2d at 31 (stating that "[p]rotecting consumers from false or misleading advertising * * * is an important goal of the statute and a laudable public policy to be served"). Thus, when the Ninth Circuit precluded private parties from challenging false and misleading advertising under the Lanham Act, it also eliminated businesses' ability to protect consumers.

The court of appeals decision most immediately and directly affects the labeling of food and beverage items. Eliminating Lanham Act claims means leaving more policing of misbranded foods to the FDA. As Pom has highlighted, *see* Pet. 25-27, the Government Accountability Office ("GAO") has specifically recognized that the FDA's efforts to regulate food labeling leave significant gaps, that the FDA is understaffed and underfunded, and that it was not aggressively policing food labeling. Precluding private parties from challenging food labels under the Lanham Act will have the practical effect of leaving food labels almost entirely unregulated. Pet. 27. The FDA "generally does not address misleading food labeling because it lacks the resources to conduct the substantive, empirical research on consumer perceptions that it believes it would need to legally demonstrate that a label is misleading." GAO 08-597, *Food Labeling: FDA Needs to Better Leverage Resources, Improve Oversight, and Effectively Use Available Data to Help Consumers Select Healthy Foods* 30 (2008) (www.gao.gov/ assets/290/280466.pdf).

Although the court of appeals limited its holding to "matters of juice beverage labeling," Pet. App. 12a, the deference given to the FDA's unexercised authority would arguably preclude a Lanham Act challenge to the label of any food, including foods that the FDA has not yet specifically addressed by regulation at all. *See* U.S. Amicus Br. 12.

The problem could be broader still, as the court of appeals' reasoning could extend to other agencies. One district court has already applied the Ninth Circuit's decision to the USDA. *See All One God Faith, Inc.* v. *Hain Celestial Grp., Inc.*, No. 09-3517,

2012 WL 3257660, at *1-11 (N.D. Cal. Aug. 8, 2012) (precluding Lanham Act claim challenging the labeling of personal care and cosmetic products as "organic" in light of the USDA's regulation of such products under the Organic Food Products Act of 1990).

While the reach of the Ninth Circuit's broad reasoning is still unknown, any preclusion of Lanham Act claims on the grounds identified by that court is too high of a price for consumers to pay. Congress enacted Section 43(a) of the Lanham Act and the FDCA for different, although in many ways complementary, purposes. This Court should give them full effect and restore to the nation's businesses and consumers the much-needed protection against the ills of false and misleading advertising.

CONCLUSION

For the foregoing reasons, the Court should reverse the judgment below.

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AMICUS CURIAE BRIEF

RECORD
AND
BRIEFS

Supreme Court, U.S.
FILED
MAR 3 - 2014
OFFICE OF THE CLERK

No. 12-761

IN THE

Supreme Court of the United States

POM WONDERFUL LLC,

Petitioner,

v.

THE COCA COLA COMPANY,

Respondent.

ON WRIT OF CERTIORARI TO
THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

BRIEF OF FORMER FDA COMMISSIONER DR. DONALD KENNEDY AS *AMICUS CURIAE* SUPPORTING PETITIONER

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BRIEF OF FORMER FDA COMMISSIONER DR. DONALD KENNEDY AS *AMICUS CURIAE* SUPPORTING PETITIONER

INTEREST OF *AMICUS*

Dr. Donald Kennedy is a former Commissioner of Food and Drugs at the Food and Drug Administration (FDA) (1977-1979).[1] After serving as FDA Commissioner, Dr. Kennedy returned to Stanford University, where he had previously been a member of the faculty. From 1980 to 1992, Dr. Kennedy served as President of Stanford University. When he stepped down, he returned to the faculty and is currently a professor emeritus. From 2000 until 2008, Dr. Kennedy also served as editor-in-chief of SCIENCE, the weekly magazine published by the American Association for the Advancement of Science.

Amicus previously expressed his views on the proper interpretation of the Food, Drug, and Cosmetic Act in *Wyeth v. Levine*, 555 U.S. 555 (2009), in a brief filed with Dr. David Kessler, another former FDA Commissioner. That brief was cited by this Court in its opinion in *Wyeth*. *See* 555 U.S. at 579 n.12.

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[1] This brief has been filed with the written consent of the parties, which is on file with the Clerk of Court. Pursuant to Rule 37.6, counsel for amicus affirms that no counsel for a party authored this brief in whole or in part, nor did any person or entity, other than amicus or his counsel, make a monetary contribution to the preparation or submission of this brief.

SUMMARY OF ARGUMENT

A private party may bring a Lanham Act challenge to a food product label regulated by the FDA under the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (FDCA). This Court can and should give effect to both the FDCA and the Lanham Act, because the requirements of both statutory schemes are complementary in this case.

The FDCA merely sets a "floor" for regulation of labels on which other laws can build. *Wyeth v. Levine*, 555 U.S. 555, 577-78 (2009). There is no conflict between the Lanham Act and FDCA – let alone an "irreconcilable" one. Here, Coca-Cola could have complied with both the FDCA's labeling regulations and the Lanham Act's ban on misleading advertising.

The Ninth Circuit erred in concluding that a Lanham Act challenge is foreclosed simply because the FDA has regulatory authority over food labeling. Such a conclusion would eliminate an important mechanism for preventing harm to consumers and competitors from false or misleading food labeling. If the FDA's regulatory authority were permitted to trump the Lanham Act, then competitors would be left without a federal remedy for false advertising that directly and substantially injures them. Such a result would run counter to congressional intent.

Moreover, the Ninth Circuit's approach would unwisely place complete responsibility for regulating food labels entirely in the hands of the FDA, which lacks the resources to perform such a daunting task. The FDA has an extremely wide range of regulatory duties, and justifiably the FDA's primary focus has been on pharmaceuticals and medical devices, not

food labels. Food labeling has traditionally been viewed as less critical to the FDA's mission than other activities.

Accordingly, it would be a mistake to read the FDCA as withdrawing the Lanham Act remedy. The two federal statutes – the FDCA and the Lanham Act, 15 U.S.C. § 1051 *et seq.* – should be interpreted as working together, not as being at odds with one another. The judgment below should be reversed.

ARGUMENT

I. The FDCA Does Not Displace The Lanham Act.

This Court has instructed that, in reconciling potentially overlapping federal statutes, courts must give full effect to both statutes unless they are in "'irreconcilable conflict.'" *Branch v. Smith*, 538 U.S. 254, 273 (2003) (quoting *Posadas v. National City Bank*, 296 U.S. 497, 503 (1936)). "[W]hen two statutes are capable of coexistence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective." *J.E M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 143-144 (2001) (citation omitted).

That task is readily accomplished here. This Court can and should give effect to both the FDCA and the Lanham Act, because this is a false advertising case in which the requirements of both statutory schemes are complementary.

Coca-Cola seeks to sell a juice product with a label that prominently displays the words "Pomegranate Blueberry." The product label also contains a large picture of a pomegranate (among

other fruits). In fact, Coca-Cola's product actually contains merely 0.3% pomegranate juice and 0.2% blueberry juice. Over 99% of the Coca-Cola product is composed of less expensive apple and grape juices.

Pom challenged Coca-Cola's labeling as misleading under the Lanham Act and California state law. Pom produced survey evidence showing that consumers are misled by Coca-Cola's label. Consumers who discovered the true composition of the Coca-Cola product complained directly to the company in substantial numbers. The federal district court noted that Coca-Cola's own internal documents reveal that the company decided it was "willing to assume the risk" of "misleading" consumers about the fact that "the product has less than 0.5% of pomegranate and blueberry juices." Pet. App. 34a-35a.

Thus, this case is precisely the kind of false advertising case traditionally covered by the Lanham Act. Nothing about the FDCA changes that conclusion. As this Court explained in a related context, the FDCA merely sets a "floor" for regulation of labels on which other laws can build. *Wyeth v. Levine*, 555 U.S. 555, 577-78 (2009). There, this Court held that the FDA's approval of a specific drug warning label did not bar state tort failure-to-warn claims based on the omission of certain information from the label. This Court observed that "Congress enacted the FDCA to bolster consumer protection against harmful products" and "did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id.* at 574, 575. That reasoning is even more persuasive in the present context, which involves the harmonization of two federal statutes rather than

the preemption of state law. *E.g.*, *Branch v. Smith*, 538 U.S. 254, 273 (2003); *J.E.M. AG Supply*, 534 U.S. at 141-44; *N.Y. Tel. Co. v. N.Y. State Dep't of Labor*, 440 U.S. 519, 540 n. 32 (1979) (plurality opinion).

There is no conflict between the Lanham Act and FDCA – let alone an "irreconcilable" one. Coca-Cola could have complied with both the FDCA's labeling regulations and the Lanham Act's ban on misleading advertising. In particular, 21 C.F.R. § 102.5(b) provides:

> The common or usual name of a food shall include the percentage(s) of any characterizing ingredient(s) or component(s) when the proportion of such ingredient(s) or component(s) in the food has a material bearing on price or consumer acceptance or when the labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient(s) or component(s) is present in an amount greater than is actually the case.

FDA rules located in 21 C.F.R. § 102.33 also address the naming and labeling of multi-juice beverages.

Coca-Cola could have complied with these rules by disclosing the amount of pomegranate juice in its product. Indeed, the regulations arguably compelled Coca-Cola to do so. For example, under 21 C.F.R. § 102.5(b), the proportion of ingredients "has a material bearing on price or consumer acceptance" of the product, and "the labeling or the appearance of" Coca-Cola's dyed-purple product "may otherwise create an erroneous impression" that pomegranate

juice "is present in an amount greater than is actually the case."

Hence, the Lanham Act and the FDCA can and do coexist. The underlying goal of the FDCA is "to protect consumers," *United States v. Sullivan*, 332 U.S. 689, 696 (1948), not to leave them vulnerable to misbranded or dangerous products. The Lanham Act was enacted "to protect persons engaged in . . . commerce against unfair competition." 15 U.S.C. § 1127; *see also Dastar Corp. v. Twentieth Century Fox Film Corp.*, 539 U.S. 23, 29 (2003). Both statutes can be given full effect.

Regulation by the FDA to ensure that food is not "misbranded" is not a substitute for Lanham Act suits. While the Lanham gives private parties a right to bring suit, the FDCA does not create a private cause of action. *See* 21 U.S.C. § 337(a). If the FDA's regulatory authority were permitted to trump the Lanham Act, then competitors would be left without a federal remedy for false advertising that directly and substantially injures them. Such a result would run counter to congressional intent.

Indeed, even in the context of preemption of *state* law, this Court has acknowledged that a federal statute will not ordinarily be construed to withdraw an available remedy to victims of an injury. In *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), for example, this Court reasoned that "[i]f Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly." *Id.* at 449; *see also Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984) (similar reasoning with respect to Atomic Energy Act).

That principle is squarely applicable here and demonstrates that the FDCA should not be construed as displacing the Lanham Act remedy.

II. The FDA Is Not Equipped To Exercise Exclusive Responsibility For Policing False Food Labels.

In many areas of the law, Congress has relied on private suits to supplement federal agency enforcement efforts. False advertising under the Lanham Act is one such example. Eliminating private enforcement efforts would have profoundly negative implications for consumers of food products and beverages throughout the Nation.

Under the Ninth Circuit's view, the task of policing false labeling would be left exclusively to the FDA. However, the FDA is in no position to address the problem of false and misleading food labeling on its own. As this Court has noted, the FDA faces severe resource constraints. *Wyeth v. Levine*, 555 U.S. at 578 n.11.

A long series of investigations and expert reports has documented the daunting challenges that the FDA faces. As an FDA advisory panel observed, since 1938, when the FDCA was enacted, Congress has adopted "125 statutes that directly impact FDA's regulatory responsibilities," by requiring "the development of implementing regulations, guidance or other types of policy, and some require the establishment of entire new regulatory programs. Virtually all require some type of scientific

knowledge or expertise for the agency to address them."[2]

The report found that, despite the addition of all of these requirements, Congress has not provided "an appropriation of new personnel and increased funding designed to allow adequate implementation." *Id.* Indeed, during the past two decades, the agency's funding and staffing levels have remained static. For these and other reasons, the report concludes that "[t]his reality, combined with a burgeoning industry . . . has made it increasingly impossible for the FDA to maintain its historic public health mission." *Id.*

The report concluded that "[t]he scientific demands on the Agency far exceed its capacity to respond. This imbalance is imposing a significant risk to the integrity of the . . . regulatory system, and hence to the safety of the public." *Id.*, at § 1.1. The report found that the agency has "serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities." *Id.* at pp. 2-3.

The Institute of Medicine has similarly warned that the FDA "lacks the resources needed to accomplish its large and complex mission."[3] As a former FDA chief counsel has observed, FDA suffers from "the hollow government syndrome—an agency with expanded responsibilities, stagnant resources,

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[2] FDA Science Board, FDA Science and Mission at Risk: A Report of the Subcommittee on Science and Technology § 2.1 (2007).

[3] The National Academies, Institute of Medicine, The Future of Drug Safety: Promoting and Protecting the Health of the Public 193 (2007).

and the consequent inability to implement or enforce its statutory mandates."[4]

Justifiably, the FDA's primary focus is on pharmaceuticals and medical devices, not food. Food labeling has traditionally been viewed as less critical to the FDA's mission than other activities. As one scholar has observed, "[t]he FDA does not have the resources to sufficiently address the current state of labeling, nor is there funding allocated to feasibly increase its enforcement power. . . . [T]he FDA has not utilized what little authority it does have to adequately address food misbranding or revise current regulations on permissible claims."[5] "Thus, the FDA's current system of enforcement is essentially based on voluntary compliance. The agency issues a Warning Letter to put a company on notice that it violated a regulation; this is typically the extent of its enforcement activity."[6]

In 2008, the GAO published an examination of the FDA's efforts to regulate food labeling.[7] Noting the FDA's severe resource constraints, GAO

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[4] Peter Barton Hutt, *The State of Science at the Food and Drug Administration*, 60 ADMIN. L. REV. 431, 431 (2008).

[5] Jennifer L. Pomeranz, *A Comprehensive Strategy to Overhaul FDA Authority for Misleading Food Labels*, 39 AM. J. LAW & MED. 617, 617 (2013).

[6] *Id.*

[7] *See* U.S. Gov't Accountability Office, GAO 08-597, Food Labeling: FDA Needs to Better Leverage Resources, Improve Oversight, and Effectively Use Available Data to Help Consumers Select Healthy Foods (2008), available at http://www.gao.gov/ assets/290/280466.pdf.

concluded that the "FDA has limited assurance that domestic and imported foods comply with food labeling requirements, such as those prohibiting false or misleading labeling."[8] Indeed, GAO observed that the FDA has itself acknowledged that it "generally does not address misleading food labeling because it lacks the resources to conduct the substantive, empirical research on consumer perceptions that it believes it would need to legally demonstrate that a label is misleading."[9]

According to the GAO, as of 2007, over 65,000 firms were subject to FDA's food regulations.[10] These firms, of course, manufacture untold numbers of many different varieties of food products. In contrast, from 2005 to 2007, the portion of the FDA Office of Nutrition, Labeling, and Dietary Supplements "dedicated to food labeling activities" had an annual budget of only "$1.1 million to $1.3 million" and had only "from 9.0 to 10.5" full-time equivalent employees.[11]

In 2011, the GAO revisited the food label issue and again concluded that the FDA needs to reassess its approach to protecting consumers from false or misleading claims.[12] The GAO recited its earlier

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[8] *Id.* at 5.

[9] *Id.* at 30.

[10] *See id.* at 51.

[11] *Id.* at 7.

[12] *See* U.S. Gov't Accountability Office, GAO 11-102, Food Labeling: FDA Needs to Reassess Its Approach to Protecting Consumers from False or Misleading Claims (2011), available at http://www.gao.gov/assets/320/314473.pdf.

finding that "FDA had little assurance that companies complied with food labeling laws and regulations for preventing false or misleading labeling, among things. We found weaknesses in FDA's oversight and use of data and resources."[13] The GAO added that the FDA has not "given its inspectors instructions for identifying potentially false or misleading information" in food labels with respect to certain kinds of claims and "does not have the ability to compel companies to turn over their substantiation documents."[14] The GAO described FDA label oversight as "minimal."[15]

These severe limitations mean that the FDA cannot serve as the exclusive entity with responsibility for food labeling. Thus, practical reasons, as well as the need to harmonize the FDCA and the Lanham Act, demonstrate that a private party should be allowed to bring a Lanham Act challenge to a food product label regulated by the FDA.

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[13] *Id.* at 8.

[14] *Id.* at i.

[15] *Id.* at 21.

CONCLUSION

The judgment below should be reversed.

Respectfully submitted,

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Dated: March 3, 2014

AMICUS CURIAE BRIEF

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United States Court of Appeals for the Ninth Circuit

BRIEF OF AMICI CURIAE PUBLIC CITIZEN, INC., AARP, CENTER FOR SCIENCE IN THE PUBLIC INTEREST, CONSUMER FEDERATION OF AMERICA, AND CONSUMERS UNION OF THE UNITED STATES, INC. IN SUPPORT OF PETITIONER

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March 2014

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INTEREST OF AMICI CURIAE[1]

Amici curiae are five consumer advocacy organizations concerned about the effects of false and misleading advertising on consumers' choices, consumers' health, and consumers' pocketbooks. Amici submit this brief because the Ninth Circuit decision finding Lanham Act claims barred by the Nutrition Labeling and Education Act poses a significant obstacle to protecting against deceptive statements in advertising.

Public Citizen is a membership organization devoted to research, advocacy, and education on a wide range of public health and consumer safety issues. Public Citizen has a longstanding interest in fighting exaggerated claims that federal regulation impliedly bars private remedies for unlawful conduct, and its lawyers have represented parties and amici in significant federal preemption cases involving the Food, Drug, and Cosmetic Act. *E.g.*, *Warner-Lambert v. Kent*, 552 U.S. 440 (2008) (Mem.); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); *Holk v. Snapple Beverage Corp.*, 575 F.3d 329 (3d Cir. 2009); *Lockwood v. ConAgra Foods*, 597 F. Supp. 2d 1028 (N.D. Cal. 2009). Public Citizen has also worked to defend consumers' access to accurate information affecting their health. *See, e.g.*, *Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council*, 425 U.S. 748 (1976); *N.Y. State Rest. Ass'n v. N.Y. City Bd. of Health*, 509 F. Supp. 2d 351, 355 (S.D.N.Y. 2007).

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[1] Pursuant to Rule 37.6 of this Court, amici curiae state that this brief was not written in whole or in part by counsel for a party and that no one other than amici curiae or their counsel made a monetary contribution to the preparation or submission of this brief. Letters from both parties consenting to the filing of this amicus brief are being submitted concurrently with this brief.

AARP is a non-profit, non-partisan membership organization that helps people turn their goals and dreams into real possibilities, strengthens communities and fights for the issues that matter most to families—such as healthcare, employment and income security, retirement planning, affordable utilities, and protection from financial abuse. As the leading organization representing the interests of people aged fifty and older, AARP seeks to protect the financial security and safety of older people, which is threatened by deceptive labeling and marketing. Consumers benefit when individuals and businesses enforce prohibitions on deceptive labeling and advertising. AARP has filed numerous amicus briefs advocating against unwarranted preemption of state laws and supporting private enforcement as essential to protect consumers, especially where the federal government does not have the resources to monitor an increasingly sophisticated barrage of marketing and labeling.

Center for Science in the Public Interest (CSPI) is a national, non-profit advocacy organization for nutrition and health, food safety, and sound science. At congressional hearings in 1989, CSPI testified in support of passage of the Nutrition Labeling and Education Act. In the 25 years since, CSPI has tirelessly advocated for effective FDA enforcement of the statute. At the same time, CSPI has used litigation under state consumer protection laws to protect consumers from misleading food and beverage labeling.

The Consumer Federation of America (CFA), an association of non-profit consumer organizations, was established in 1968 to advance the consumer interest through research, advocacy, and education. Today, nearly 300 of these groups participate in the federation. As a research organization, CFA researches consumer issues and publishes its findings in reports that assist consumer

advocates, policymakers, and individuals. As an advocacy organization, CFA works to advance pro-consumer policies on a variety of issues before Congress, the White House, regulatory agencies, state legislatures, and the courts. As an education organization, CFA disseminates information on consumer issues to the public, news media, policymakers, and other public interest advocates. CFA's Food Policy Institute was established in 1999 to promote a safer, healthier, and more affordable food supply. The Institute supports reform of federal food safety programs, changes in federal food regulations to encourage production and marketing of healthier foods, and policies to ensure consumers have adequate and accurate information to make informed choices in the marketplace.

Consumers Union of the United States, Inc. is a nonprofit organization based in Yonkers, New York that does business as Consumer Reports. The country's largest consumer research, testing, and advocacy organization, Consumer Reports was founded in 1936 with the mission of promoting a fair, just, and safe marketplace for all consumers and empowering consumers to protect themselves. The organization has a citizen activist base of more than 1 million people, and its various print and digital publications have a combined subscribership of more than 8 million people. Consumer Reports employs policy experts, lobbyists, grassroots organizers, and outreach specialists who work with the organization's grassroots activists to change legislation and the marketplace in favor of the consumer interest. Since its inception, Consumer Reports has engaged in research, advocacy, and public education with the goal of exposing and countering misleading advertising and claims. To that end it has focused on food safety and truth in labeling, and has

lobbied and litigated against federal preemption of pro-consumer laws in this area.

STATEMENT

A. Regulation of Food Labeling Under the NLEA

Under the Food, Drug, and Cosmetic Act (FDCA), the Food and Drug Administration (FDA) regulates certain aspects of food safety and labeling. In 1990, Congress enacted the Nutrition Labeling and Education Act, Pub. L. No. 101-535, 104 Stat. 2353, 2364 (1990) (NLEA), codified as part of the FDCA, to augment the FDA's authority over food labeling. Among other things, the NLEA requires that nutrition labeling be placed on most packaged food, prohibits the use of terms that characterize the level of nutrients in a food unless they conform to definitions established by the FDA, and ensures that claims about the relationship between nutrients and health conditions are supported by significant scientific agreement.

The FDA can address violations of NLEA requirements by exercising its power under the FDCA to initiate enforcement proceedings against manufacturers of misbranded food. 21 U.S.C. §§ 332-334; *see id.* § 343 (defining "misbranded"). A food labeled in violation of FDCA or NLEA requirements may be deemed misbranded because its labeling is "false or misleading in any particular," *id.* § 343(a)(1), or because its label does not contain required nutrition information (such as serving size, number of servings per container, or total number of calories). *Id.* § 343(q).

Although neither the NLEA nor the FDA regulations implementing it require prior approval of juice names or labeling, they address a few discrete aspects of mixed-juice products. The NLEA provides that, if a beverage purports to contain fruit juice—including by using the

name of a fruit in the product name—the label must disclose the percentage of the named fruit contained in the product. 21 U.S.C. § 343(i); *see* 21 C.F.R. § 101.30. A beverage labeled as a juice must state the "common or usual name" of the beverage, *id.*, which "shall be a descriptive name" that "shall accurately identify or describe, in as simple and direct terms as possible, the basic nature of the food and its characterizing ingredients." *Id.* § 102.5. Fruit juices identified on the label (other than in the ingredient statement) must be listed in descending order of predominance. *Id.* § 102.33(b). Generally, if the product contains only minor amounts of fruit juice for flavoring and the label uses a descriptive word such as "flavoring," these requirements do not apply. *Id.* §§ 101.30(c), 102.33(b). If, however, "the proportion of [a characterizing ingredient] in a food has a material bearing on price or consumer acceptance, or when the label or labeling or the appearance of the food may otherwise create an erroneous impression that such ingredient[] ... is present in an amount greater than is actually the case," the percentage of the ingredient "shall be declared" as a part of the common or usual name of the food. *Id.* § 102.5(b); 58 Fed. Reg. 2897, 2920 (1993) (final rule).

The statutory provision and the implementing regulations regarding disclosure of juice content were motivated by concern that beverage labels referring to or depicting fruits were misleading to consumers with regard to the overall juice content and the healthiness of the product. *See generally* 58 Fed. Reg. 2897; 56 Fed. Reg. 30452 (1991) (proposed rule).

B. The NLEA's Preemption Provision

In enacting the NLEA, Congress did not address preclusion of other federal laws, such as the Lanham Act. It did, however, devote careful attention to the related

subject of the extent to which the legislation would preempt state laws. *See* Laura Sims, *The Politics of Fat: Food and Nutrition Policy in America* 199 (1998) ("The preemption issue remained a key area of dispute throughout consideration of the food labeling bill, with the basic issue being how far the legislation should go in setting uniform food labeling regulations that preempt state laws."). In the final moments of the floor debate before the NLEA was passed in the House of Representatives, Representative Waxman explained that a narrow preemption provision had been added to the bill to induce the food industry to support the legislation. 136 Cong. Rec. H12951-02, H12954 (Oct. 26, 1990) ("[I]t was decided that the fairest way to expect the food industry to support a nutrition labeling bill, was to give them some types of preemption of some burdensome State laws that interfered with their ability to do business in all 50 States."). The leading proponent of stronger federal preemption, Senator Orrin Hatch, agreed that "the carefully crafted uniformity section of this legislation is limited in scope." 136 Cong. Rec. S16607-02, S16611 (Oct. 24, 1990).

The express preemption provision of the NLEA, codified at 21 U.S.C. § 343-1(a), carefully specifies and limits the subjects on which federal standards will preclude enforcement of non-identical state laws. Under that section, state "requirements" that are "not identical" to federal requirements addressing twelve specified topics are preempted. For example, states may not impose a "standard of identity" on a food subject to an FDA standard of identity, unless the state standard is identi-

cal to the federal standard. *Id.* § 343-1(a)(1).[2] And states may not impose requirements related to nutrition labeling (the statement of serving size, calories, etc., required on food packages) or requirements regarding labeling that characterizes the level of nutrients or makes health claims related to nutrients, unless those state requirements are identical to federal requirements. *Id.* § 343-1(a)(4)-(5).

The only provision of the express preemption provision, § 343-1(a), that specifically addresses fruit juice is paragraph 2, which provides that states may not impose non-identical "requirement[s] for the labeling of food of the type required by" § 343(i)(2). That provision in turn provides that beverages purporting to contain fruit juice must prominently disclose the percentage of juice contained in the beverage. The provision is not implicated here, as none of the claims seek to enforce requirements for listing percentages of juices (although listing the tiny percentages of pomegranate and blueberry juices in the product is one way in which Coca-Cola could have ameliorated the misleading nature of the label at issue here).

In addition, paragraph 3 of the express preemption provision provides that states may not impose any non-identical "requirement for the labeling of food of the type required by" § 343(i)(1). That provision in turn provides that a food label must bear the common or usual name of the food (or beverage). The provision would be informative here, although not dispositive, if POM's challenge were limited to the propriety of a name that complied

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[2] A standard of identity is a regulatory definition of what ingredients are required to be or prohibited to be in a food product that is sold under a particular name. *See, e.g.*, 21 C.F.R. § 139.110 (setting standard of identity for macaroni products).

with § 343(i)(1) and related regulations. *See also* 58 Fed. Reg. at 2920 (regulation concerning naming of juice "does not relieve the manufacturer of the obligation to label the product in a truthful and nonmisleading manner").

Notably, § 343(a)(1), which prohibits food labeling that "is false or misleading in any particular" is not among the types of requirements listed as having preemptive effect in § 343-1(a). Thus, the express preemption provision does not bar the enforcement of state laws imposing requirements of that type—that is, requirements addressing false or misleading labels.

The NLEA's very specific limitations on the types of requirements that displace state laws reflect an effort to satisfy industry concerns while remaining "sensitive to the regulatory roles played by the States." 136 Cong. Rec. at S16609 (Sen. Mitchell). The preemption provision was "refined to provide national uniformity where it is most necessary, while otherwise preserving State regulatory authority where it is appropriate." *Id.*; *see also* 136 Cong. Rec. at S16611 (Sen. Hatch) ("[T]he compromise makes clear that the national uniformity in food labeling that is set forth in the legislation has absolutely no effect on preemption of State or local requirements that relate to such things as warnings about foods or components of food.").

To make clear that, aside from § 343-1(a), the new labeling laws would, as Senator Mitchell said, "otherwise preserv[e] State regulatory authority," Congress added § 6(c) of the NLEA. Section 6(c) precludes implied preemption of state laws by limiting the scope of preemption to the areas specified in the express preemption provision:

> The Nutrition Labeling and Education Act of 1990 shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under section 403A [21 U.S.C. § 343-1(a)] of the Federal Food, Drug, and Cosmetic Act.

Pub. L. No. 101-535, § 6(c), 104 Stat. at 2364 (21 U.S.C. § 343-1 note).

Section 6(c) makes explicit that the NLEA does not preempt, either expressly or impliedly, state requirements concerning aspects of fruit juice labeling not specified in § 343-1(a). And nothing in the NLEA addresses preclusion of claims that might be otherwise available under federal law.

SUMMARY OF ARGUMENT

POM Wonderful LLC (POM) brought this action against the Coca-Cola Company, stating a false-advertising claim under the Lanham Act and claims under California's Unfair Competition Law and False Advertising Law. At issue here is the claim that Coca-Cola's advertising, name, and labeling of its Minute Maid "Pomegranate Blueberry" juice are false or misleading, in violation of the Lanham Act, 15 U.S.C. § 1125(a).

The court below held that POM's Lanham Act claim is barred by the FDA's "comprehensive" regulation of beverage labeling. The court did not suggest that the product's label was not misleading to consumers. Instead, the court held that the Lanham Act claim "would risk undercutting the FDA's expert judgment and authority." Pet. App. 11a, 12a.

Where two federal statutes pose no irreconcilable conflict and Congress has not stated its intent to oust operation of either, this Court presumes both to be effective. Here, both the NLEA and the Lanham Act easily

can co-exist, and, therefore, the decision below was incorrect. Congress's unusually clear instruction in 21 U.S.C. § 343-1(a) and § 6(c) of the NLEA as to the preemptive scope of the NLEA with regard to state law reinforces this conclusion. Through those provisions, Congress specified that a state-law claim that is substantially similar to POM's Lanham Act claim is not preempted. Congress thus specified that such challenges pose no threat to FDA regulation. If enforcement of state laws on these subjects is not inconsistent with the NLEA, it follows that enforcement of other federal laws that address these subjects also is not inconsistent with the NLEA. Likewise, Congress's careful delineation of the preemptive scope of the NLEA belies the notion that the FDA occupies the field so as to bar Lanham Act claims.

In addition, "Congress enacted the FDCA to bolster consumer protection against harmful products." *Wyeth v. Levine*, 555 U.S. 555, 574 (2009). Just as in the context of prescription drugs, reading the statute broadly to bar private rights of action with respect to food labeling "is at odds with what evidence we have of Congress' purposes." *Id.* at 577. And just as in the context of prescription drugs, private rights of action challenging aspects of food labeling over which manufacturers exercise control are not barred by the FDCA and FDA regulation under it.

Finally, the FDA has acknowledged that it does not have the resources to address and does not address misleading food and beverage labeling. Private enforcement is therefore the only existing mechanism for deterring and addressing misleading food labeling.

ARGUMENT

I. The NLEA's Disavowal of Implied Preemption of State-Law Claims Shows That Federal Lanham Act Claims Likewise Are Not Impliedly Barred.

A. The NLEA Devotes Careful Attention to Preemption but Includes No Provision Suggesting That Lanham Act Claims Are Barred.

In the NLEA, Congress set forth, in unusually specific fashion, which federal requirements would preempt non-identical state requirements, and foreclosed any attempt to give the statute a broader preemptive reading. 21 U.S.C. § 343-1(a) & note (§ 6(c)). Two aspects of § 343-1(a) are significant here. First, the provision preserves laws that would impose requirements "identical" to the specified federal requirements and, therefore, does not preempt private remedies for violations of those requirements. Thus, the NLEA does not preempt a challenge to a juice name where the name does not comply with federal requirements, or where the challenge is based on advertising, rather than labeling. *See id.* § 343-1(a)(3). Second, the preemption provision does not reach the descriptive content of beverage labeling or advertising.[3] Accordingly, state-law claims challenging the descriptive labeling of a juice beverage are not preempted: "The NLEA explicitly forecloses the possibility that state law would be impliedly preempted." *N.Y. State Rest. Ass'n v. N.Y. City Bd. of Health*, 509 F. Supp. 2d 351, 355 (S.D.N.Y. 2007) (citing NLEA § 6(c), 21 U.S.C.

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[3] As used here, "descriptive content" refers to aspects of labeling other than the nutrition panel, ingredient lists, common name, and percentage-of-juice statements that are specified as preemptive requirements in § 343-1(a).

§ 343-1 note). *Accord Holk v. Snapple Bev. Corp.*, 575 F.3d 329, 337 (3d Cir. 2009); *Lockwood v. ConAgra Foods*, 597 F. Supp. 2d 1028, 1032 (N.D. Cal. 2009); *see also Brazil v. Dole Food Co.*, 935 F. Supp. 2d 947, 957 (N.D. Cal. 2013).

As the FDA has explained, § 6(c) of the NLEA "clearly manifests Congress's intention" that the NLEA not preempt state law beyond the NLEA's express terms: "If there is no applicable Federal requirement that has been given preemptive status by Congress, there is no competing claim of jurisdiction, and, therefore, no basis under the 1990 amendments for Federal preemption." 56 Fed. Reg. 60528, 60530 (1991).

Thus, Congress has directed and the FDA has recognized that "the *only* State requirements that are subject to preemption are those that are affirmatively different on matters that are covered by section [343-1] of the act." 58 Fed. Reg. 2462 (1993) (emphasis added). In this respect, the NLEA's preemption provisions are "somewhat unusual," in that, when considering state-law claims, "[t]he NLEA can be analyzed only in terms of express preemption, because its express provisions prohibit any implied preemption under the statute." Burk, *The Milk-Free Zone: Federal and Local Interests*, 22 Colum. J. Envt'l L. 227, 259 (1997); *accord In re Farm Raised Salmon*, 175 P.2d 1170, 1179 (Cal. 2008).

As relevant here, under the NLEA, a *state-law* claim challenging the "common or usual name" of a juice beverage would be expressly preempted if that name complied with 21 C.F.R. §§ 102.5 and 102.33—the FDA regulations that address "common or usual names" generally and for fruit juices. The product name "Pomegranate Blueberry," however, does not seem to comply with those regulations because the name does not include

"blend," "flavored," or other such qualifiers, and does not state the percentage of the "characterizing ingredients," pomegranate and blueberry. A *state-law* claim challenging that name as misleading would therefore not be barred to the extent that it sought to enforce a requirement identical to these federal requirements.[4] Moreover, because the applicable paragraph of the NLEA's preemption provision applies only to requirements for "the labeling" of food, it likewise does not bar a state-law claim premised on misleading use of a name in advertising.

Similarly, a state-law claim challenging a juice beverage label as a whole (as opposed to the name in particular) as misleading—for example, because the label highlights pomegranate and blueberry when the beverage in fact it contains only 0.3% pomegranate and 0.2% blueberry juice (particularly if the percentages are not disclosed on the label)—is not barred. To the contrary, because the claim does not fall under any paragraph of § 343-1(a), which defines the express preemptive scope of the NLEA, and because Congress has specified that the

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[4] The parties apparently disagree about whether the name of Coca-Cola's product as displayed on its label is "Pomegranate Blueberry," as POM contends, or "Pomegranate Blueberry Flavored Blend of 5 Juices," as Coca-Cola argues. Pet. App. 1a-2a. That dispute turns on whether additional words placed in smaller print on a different line of the label are part of the name. The disagreement is noted in the opinion below, and although the court stated that it took "no view" on the disagreement, *id.* 2a, the court in reaching its holding seemed to assume that the name was "Pomegranate Blueberry Blend of 5 Juices." *Id.* 9a. Resolution of this dispute would not determine whether the NLEA would expressly preempt a state-law claim challenging that name, as the dispute does not address the requirements of 21 C.F.R. § 102.5(b), concerning the treatment of characterizing ingredients in the product's common or usual name.

NLEA "shall not be construed to preempt any provision of State law, unless such provision is expressly preempted" under § 343-1(a), such a state-law claim is expressly *not* preempted.

The NLEA's state-law preemption provisions (including § 6(c), the no-implied-preemption provision) weigh strongly against reading the statute to bar Lanham Act claims: A Congress so concerned with precisely defining the types of laws displaced by the NLEA surely would have mentioned the Lanham Act or other federal laws had it intended to foreclose their application.

Further, the Lanham Act creates a private right of action against any person who makes false and deceptive statements in a commercial advertisement about its product or on the product container. 15 U.S.C. § 1125(a). POM's claim thus has much in common with claims under the unfair and deceptive acts and practices statutes of the 50 states. *See, e.g.*, Cal. Bus. & Prof'l Code § 17200 (creating a cause of action against unfair or fraudulent business acts or practices and unfair, deceptive, untrue, or misleading advertising). Given that a state-law claim substantially similar to POM's Lanham Act claim is not preempted—because Congress has expressly so stated—Coca-Cola's position would create the odd scenario in which one federal law would be deemed to bar operation of another, but to leave a similar state law untouched.

This illogical outcome reveals the flaw in the decision below. The purported justification for barring Lanham Act claims is refuted by Congress's decision *not* to bar substantially similar state-law claims. As in the context of preemption of state law, "[i]f there is no Federal requirement to be given preemptive effect, preemption [or

here, preclusion] does not occur." 60 Fed Reg. 57076, 57120 (1995) (FDA statement).[5] And "when two [federal] statutes are capable of co-existence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective." *Morton v. Mancari*, 417 U.S. 535, 551-52 (1974) ("When there are two acts upon the same subject, the rule is to give effect to both if possible . . . . The intention of the legislature to repeal 'must be clear and manifest.'" (quoting *United States v. Borden Co.*, 308 U.S. 188, 198 (1939))); *see Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 662-63 (2007). If state requirements can coexist with the NLEA, it necessarily follows that similar requirements imposed by other *federal* laws can likewise coexist.

B. The NLEA Does Not Occupy the Field of Beverage Labeling.

The decision below suggests that the FDA occupies the field of beverage labeling. Pet. App. 12a ("We are primarily guided in our decision ... by Congress's decision to entrust matters of juice beverage labeling to the FDA and by the FDA's comprehensive regulation of that labeling."). Preemption or preclusion based on this theory applies, however, only when the "scheme of federal regulation" is "so pervasive as to make reasonable the inference that Congress left no room for the States [or other federal law] to supplement it." *English v. General Elec. Co.*, 496 U.S. 72, 79 (1990) (citation omitted). No

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[5] In other settings, courts have recognized that whether a federal law displaces another exercise of federal authority is governed by principles similar to federal-state preemption. *See, e.g., Chamber of Commerce v. Reich*, 74 F.3d 1322, 1334 (D.C. Cir. 1996).

such federal scheme exists here.[6] Rather, the NLEA itself makes plain that Congress did not intend to occupy the field of food labeling in general or beverage labeling in particular.

Section 343-1(a) identifies very specifically which statutory provisions preempt state law, and § 6(c) states unequivocally that state law outside the scope of § 343-1(a) is not preempted. "Congress' enactment of a provision defining the pre-emptive reach of a statute implies that matters beyond that reach are not pre-empted" under field preemption principles. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 517 (1992); *see also Wis. Pub. Intervenor v. Mortier*, 501 U.S. 597, 613 (1991) (express preemption provision would be "pure surplusage if Congress had intended to occupy the entire field"). Thus, even absent § 6(c), the statute's limited express preemption provision would impliedly foreclose the conclusion that Congress intended to occupy the field of food and beverage labeling. Here, where § 6(c) expressly disclaims any such intention, the conclusion is even clearer. The NLEA's limited express preemption provision and its anti-implied preemption provision manifest that Congress did not intend to displace all other law with regard to food labeling.

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[6] *Cf. Sprietsma v. Mercury Marine*, 537 U.S. 51, 69 (2002) (no field preemption where Coast Guard authorized to regulate boat safety but statute "does not *require* the Coast Guard to promulgate comprehensive regulations covering every aspect of recreational boat safety and design") (emphasis in original).

II. The FDA Does Not Police the Type of Misleading Labeling Alleged Here.

A. Lanham Act Claims Do Not Challenge the FDA's Expert Determinations.

The court below held that, if POM were to succeed in its Lanham Act challenge to the product's name, the finding that the name was misleading "would create a conflict with FDA regulations and would require us to undermine the FDA's apparent determination that so naming the product is not misleading." Pet. App. 9a. With respect to the presentation of the product's label, the court reached a similar conclusion, finding that the claim "would risk undercutting the FDA's expert judgments and authority." *Id.* 11a.

In addition to being incorrect in believing that POM's challenge to the name of Coca-Cola's beverage conflicted with the FDA's product-name regulations, the appellate court was wrong to worry that the Lanham Act claims would challenge the FDA's expert determination about beverage labeling. FDA regulations about fruit juice labeling set forth a small number of requirements for labeling of mixed-juice beverages. *See supra* p. 5. The regulations, however, give companies substantial autonomy in crafting labeling, and companies are free to go beyond the regulatory requirements. For example, no FDA regulation required Coca-Cola to make pomegranate or blueberries predominant images on the label. And Coca-Cola would not have run afoul of any FDA requirement by stating, for example, "a blend of 3 juices, with a splash of pomegranate and blueberry." That is, nothing in the NLEA or the applicable regulations precludes a company from *both* complying with FDA fruit-juice regulations *and* giving consumers a clear understanding of a product's juice content. *See also Morton*, 417 U.S. at 551

(overlapping statutes capable of co-existence should be regarded as effective, unless Congress clearly states otherwise). Under this regulatory scheme, for claims that do not implicate a topic specified in the express preemption provision, concern about infringing on the FDA's decisionmaking is misplaced.

Further, for matters beyond the scope of express preemption, there is no policy basis for precluding application of the Lanham Act because—even leaving aside that the NLEA specifies that it does not impliedly bar the application of other laws—there is no conflict that would support implied preemption here. Rather, the purpose of the pertinent FDA requirements is to ensure that beverages that purport (through names, descriptions, or pictures on labeling or advertising) to contain juice do not mislead consumers by creating a false impression about juice content. *See generally* 58 Fed. Reg. 2897 (discussing reasoning behind rule requiring percentage disclosure); *see also id.* at 2919 (explaining that 21 C.F.R. § 102.33 reflects an attempt to address the problem that "beverage labels are clearly misleading if they misrepresent the contribution of one or more individual juices to the nature of the product").

Lanham Act claims alleging misleading advertising or labeling are consistent with and pose no obstacle to the accomplishment of the purpose behind these federal requirements. Indeed, the objectives are the same—to prevent misleading labeling. Requirements of federal law generally do not preclude enforcement of other laws aimed at the same or consistent objectives. *Cf. Hillsborough County v. Auto. Med. Labs.*, 471 U.S. 707, 717 (1985) ("[M]erely because the federal provisions were sufficiently comprehensive to meet the need identified by Congress did not mean that States and localities were

barred from identifying additional needs or imposing further requirements in the field.").

B. The Decision Below Is Inconsistent with *Wyeth v. Levine.*

Importantly, the FDA exercises far less careful oversight over beverage labeling than over drug labeling. Drug manufacturers must not only comply with general FDA regulations about labeling, they must also obtain FDA approval of the specific labeling they wish to use. 21 U.S.C. § 335(b); *see also* 21 C.F.R. § 314.50(c)(2)(i). Approval of the labeling is part of the approval required as a precondition to marketing the product at all, and all changes to labeling must be run past the FDA (either in advance or when made). 21 C.F.R. § 314.80. Yet, as this Court has confirmed, FDA approval of a drug's labeling does not preclude state-law claims challenging the adequacy of that labeling. *See Wyeth v. Levine*, 555 U.S. 555. Rather, the Court recognized that the approved labeling sets not a ceiling, but a floor, establishing minimum standards. State-law challenges to labeling "lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times." *Id.* at 579; *see id.* at 583 (Thomas, J., concurring in the judgment) (agreeing that, in light of regulations allowing labeling changes, "federal law does not give drug manufacturers an unconditional right to market their federally approved drug at all times with the precise label initially approved by the FDA").

FDA regulation of beverage labeling does not begin to approach the level of FDA regulation of drug labeling. Unlike the regulatory scheme applicable to drugs, the FDA does not approve beverage names or labeling, matters over which companies have significant freedom. For instance, although some FDA regulations are applicable

to beverage labeling generally, the FDA has never evaluated the name or labeling of the Minute Maid juice at issue, much less made a determination that the name and labeling are or are not misleading.

In short, the FDA's significantly greater regulation of drugs and this Court's recognition in *Wyeth* that claims challenging aspects of drug labeling are not barred directs the answer to the question presented here. Congress cannot have intended to create a scheme whereby claims challenging misleading drug labeling could go forward (as this Court has held) but claims about misleading beverage labeling are impliedly barred (as the lower court held).

C. Private Enforcement Is the Primary Mechanism for Addressing and Redressing Misleading Labeling.

Congress's decision to carefully limit the preemptive scope of the NLEA reflects a recognition that the FDA is not equipped to act as the sole monitor of the expansive marketplace for foods and beverages. The NLEA was enacted, in part, to address a sizable increase in "unfounded health claims ... being made in the marketplace." H. Rep. No. 101-538, at 9 (1990) (quoting then-FDA Commissioner Sullivan). To find preclusion here would mean that, in seeking to expand oversight of misleading food labeling, Congress implicitly cut back on existing tools for doing so. This result is neither required by nor consistent with the NLEA.

The oversight role of competitors and consumers is particularly important because the FDA lacks the resources to handle the task alone. As the Government Accountability Office (GAO) reported in 2008, "FDA has limited assurance that domestic and imported foods comply with food labeling requirements, such as those

prohibiting false or misleading labeling." GAO, *Food Labeling: FDA Needs to Better Leverage Resources, Improve Oversight, and Effectively Use Available Data to Help Consumers Select Healthy Foods* 5, 13 (2008), *available at* www.gao.gov/new.items/d08597.pdf. In addition, the GAO stated that the "FDA has reported that limited resources and authorities significantly challenge its efforts to carry out food safety responsibilities—challenges that also impact efforts to administer and enforce labeling requirements." *Id.* at 6.

Perhaps most significant here, "according to FDA officials, the agency generally does not address misleading food labeling because it lacks the resources to conduct the substantive, empirical research on consumer perceptions that it believes it would need to legally demonstrate that a label is misleading." *Id.* at 30. The FDA's online list of enforcement actions bears out this fact. From February 1, 2013, through February 1, 2014, the FDA sent only one warning letter concerning a food labeled in a misleading way. *See* Letter from FDA to John Stanger, dated July 26, 2013, *available at* www.fda.gov/ICECI/EnforcementActions/WarningLetters/2013/ucm364729.htm (label inaccurately stated that products were "all natural" and contained cheddar cheese, among numerous other violations).

Although the FDA's Office of Food Safety and Applied Nutrition does take enforcement actions, its labeling-related actions are almost exclusively concerned with specific violations of specific statutory requirements: failure to properly format the nutrition labeling panel, a topic on which the FDA regulations are extremely specific, *see* 21 C.F.R. § 101.9; or labeling that includes drug claims, *see* 21 C.F.R. §§ 101.72-101.83. These FDA enforcement efforts are important. They do not obviate,

however, the problem of labeling that misleads consumers without violating a specific FDA requirement (aside from the general prohibition against misleading labeling). For that problem, private enforcement is the only mechanism for deterring, addressing, and redressing misleading labeling.

CONCLUSION

For the foregoing reasons, the decision below should be reversed insofar as it held POM's Lanham Act claims barred by the FDCA.

Respectfully submitted,

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March 2014